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Vol 4 of 4





U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511C)
1200 Pennsylvania Avenue NW
Washington, DC 20460

EPA Reg. Number:

524-528

Date of Issuance:

Term of Issuance:

Conditional

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Name of Pesticide Product:

Corn Event MON863

Name and Address of Registrant (include ZIP Code):

Monsanto Company
700 Chesterfield Parkway West
St. Louis, MO 63017

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on her motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

The registration application referred to above, submitted in connection with registration under § 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you implement the following terms and conditions.

- 1) The subject registration will automatically expire on midnight May 1, 2004. The registration must expire on this date because this is the date of expiration of the tolerance exemption under 40 CFR 180.1214. When and if the Agency registers this product, it is our understanding that Monsanto intends to submit in the near future an amendment application to modify the expiration date and a petition to amend the tolerance exemption under 40 CFR 180.1214 so that its expiration date is removed. Based on the Agency's review of the data submitted and cited in support of this application, and provided that the Agency finalizes a rule which amends 40 CFR 180.1214 so that its expiration date is removed; the Agency anticipates at this time that an expiration date three years from the initial date of registration for this product would be appropriate.
- 2) The subject registration will be limited to *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Material Necessary for its Production (Vector ZMIR13L) in Event MON863 Corn use in field corn.
- 3) Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires registrants of similar products to submit such data.

Signature of Approving Official:

JTH see last page

Date:

4) Submit production information for this product to Mr. Owen Beeder of Office of Pesticide Programs, Registration Division (mail code 7505C) for the fiscal year in which this product is conditionally registered, in accordance with FIFRA § 29. The fiscal year begins October 1 and ends September 30. Production information will be submitted to the Agency no later than December 15, following the end of the preceding fiscal year.

5) Submit independent laboratory method validation (under OPPTS Guidelines 860.1340) to complete the database for Cry3Bb1 corn within 12 months of the date of registration. Provide to the EPA laboratory (Ft. Meade, MD) methodology and/or reagents necessary for validation of a Cry3Bb1 analytical method within 6 months of the date of registration. The extraction and detection method as described for Cry3Bb1 protein appears to be adequate for analysis of Cry3Bb1 protein in corn grain. However, this method must be validated by both an independent laboratory and the EPA Biological and Economic Analysis Division laboratory before it can be considered a valid method. In addition, to assure that grain handlers have a test method in place prior to harvest, you must make available Cry3Bb1 strip tests to grain handlers and demonstrate to the Agency this provision prior to September 2003. EPA understands that these are 'qualitative' test kits and that you are in discussions with USDA/GIPSA about providing methodology and reagents for their use in developing a validated 'quantitative' method for MON 863 and that this transfer of materials will take place once registration occurs.

6) Submit expression data in terms of dry weight, as the amount of protein present in the given tissue. Tissues for which expression data must be provided include: leaf, root, pollen, seed, and whole plant. In addition, data for each of these tissues should be provided for young plants in rapid growth, during flowering, and mature plants before harvest when that part of the plant is present. Data obtained for roots should also include typical times when corn rootworm would be feeding. Data are due within 24 months of the date of registration, provided the registration is amended to extend the registration date.

7) Submit field degradation studies evaluating accumulation and persistence of Cry3Bb1 in several different soils in various strata. Representative fields must have been planted with MON863 and include both conventional tillage and no-till samples and be harvested under typical agronomic conditions. Sampling must continue until the limit of detection is reached. Studies should include soils with high levels of a variety of clays. Both ELISA and insect bioassays need to be conducted and compared to determine if Cry3Bb1 is accumulating or persisting in soil samples. A protocol is due within 90 days of the date of registration, and a progress report is due within one year of the date of registration. If the registration and tolerance exemption are amended to extend the expiration dates, a final report is due two years from the date of registration.

8) Submit laboratory toxicity tests with *Orius insidiosus* (minute pirate bug), carabid (ground beetle), and *Tetraopes* (red milkweed beetle) within 24 months of the date of registration, provided the registration is amended to extend the registration date. Protocols are due within 120 days of the date of registration.

9) Full-scale field or semi-field studies with appropriate end points and statistical power must be conducted. Submit intermediate and multi-year non-target organism field studies with statistical power. You must submit final results to field studies previously summarized in MRID No.456530-03 (the carabid and nematode data are of particular interest) and annual reports each year of this registration every April 30th.

10) Submit a six week broiler dietary study with 60% - 70% MON 863 corn in the diet that is of appropriate duration to represent the start and growing periods of the test species. Balanced diets should be formulated according to the National Research Council guidelines ("Nutrient Requirements of

Poultry," Ninth Revised Edition, 1994) with the energy requirements of the test species being met by the inclusion of corn in the diet to assess hazards from chronic exposure of wild or domesticated fowl. A protocol for poultry studies must be submitted within 90 days of the date of registration with a final report submitted 18 months after approval of the protocol.

11) Submit the following insect resistance management/pest biology data. Protocols and data sets identified in Monsanto's 12/13/2002 letter must be submitted within 90 days of the date of registration. A progress report must be submitted by January 31, 2004. Provided the registration is amended to extend the expiration date, the final reports must be submitted by January 31, 2006.

- Research regarding adult and larval movement and dispersal, mating habits, ovipositional patterns, number of times a female can mate and fecundity.
- Research to determine if IRM strategies designed for WCRW and NCRW are appropriate for MCRW
- Research regarding the mechanism of potential resistance of CRW to MON 863 is necessary to develop an appropriate long-term IRM strategy. Monsanto must attempt to develop resistant CRW colonies to aid in determining selection intensity.
- Research regarding the effect of WCRW ovipositing in soybean prior to overwintering and extended diapause in NCRW on an IRM strategy needs further investigation.
- Detailed summaries of the four data-sets identified in Monsanto's December 13, 2002 letter should be submitted to the Agency to support their conclusion that the initial resistance allele frequency is ≤ 0.01 .
- Baseline susceptibility studies currently underway should be continued for WCRW and initiated for NCRW and monitoring techniques such as discriminating dose concentration assays need to be thoroughly investigated for their feasibility as resistance monitoring tools.

12) BPPD strongly urges Monsanto to submit data and information cited in the benefits assessment (contained in the MON863 Biopesticides Regulatory Action Document) to help measure the impacts and potential benefits of the use of MON 863 corn on a wide scale. [Note that this is not a required term or condition of the registration.]

13) You must implement the following Insect Resistance Management Program:

The required IRM program for Cry3Bb1 *Bt* corn has the following elements:

- 1] Requirements relating to creation of a non-Cry3Bb1 *Bt* corn refuge in conjunction with the planting of any acreage of commercial Cry3Bb1 *Bt* corn;
- 2] Requirements for the registrants to prepare and require Cry3Bb1 *Bt* corn users to sign "grower agreements" which impose binding contractual obligations on the grower to comply with the refuge requirements;
- 3] Requirements for the registrants to develop, implement, and report to EPA on programs to educate growers about IRM requirements;

- 4] Requirements for the registrants to develop, implement, and report to EPA on programs to evaluate and promote growers' compliance with IRM requirements (the Cry3Bb1 Compliance Assurance Program (CAP) must integrate with the CAP already approved for MON810, EPA Registration Number 524-489);
- 5] Requirements for the registrants to develop, implement, and report to EPA on monitoring programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry3Bb1 protein in the target insects;
- 6] Requirements for the registrants to develop, and if triggered, to implement a "remedial action plan" which would contain measures the registrants would take in the event that any insect resistance was detected as well as to report on activity under the plan to EPA;
- 7] Submit annual reports on sales (by state and county), IRM grower agreements results, compliance, and educational program on or before January 31st each year beginning in 2004.

a. Refuge Requirements

Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- Specifically, growers must plant a structured refuge of at least 20% non-Cry3Bb1 *Bt* corn that may be treated with insecticides as needed to control corn rootworm larvae. Growers will not be permitted to apply CRW labeled insecticides to the refuge for control of insect pests while adult corn rootworm are present unless the Cry3Bb1 field is treated in a similar manner.
- Refuge planting options include: refuge acres should be planted as blocks adjacent to MON 863 corn fields or as in-field strips.
- External refuges must be planted adjacent to Cry3Bb1 MON 863 fields.
- When planting the refuge in strips across the field, refuges must be at least 6 rows wide, preferably 12 consecutive rows wide.
- Insecticide treatments for control of corn rootworm larvae may be applied. Instructions to growers will specify that insecticides labeled for control of corn rootworm adults cannot be applied while adults are present in the refuge unless the Cry3Bb1 field is treated in a similar manner.

b. Grower Agreements

- 1] Persons purchasing the *Bt* corn product must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.
- 2] The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
- 3] The registrant must develop a system (equivalent to what is already approved for MON 810, EPA Reg. No. 524-489) which is reasonably likely to assure that persons purchasing the *Bt* corn product will affirm

annually that they are contractually bound to comply with the requirements of the IRM program. The proposed system will be submitted to EPA within 90 days from the date of registration.

4] The registrant must use grower agreements and submit to EPA within 90 days from the date of registration a copy of that agreement and any specific stewardship documents referenced in the grower agreement. If Monsanto wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty days prior to implementing a proposed change, the registrant must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of the amendment.

5] The registrant must establish a system (equivalent to what is already approved for MON 810, EPA Reg. No. 524-489) which is reasonably likely to assure that persons purchasing the *Bt* corn sign grower agreement(s), and must provide within 90 days from the date of the registration a written description of that system.

6] The registrant shall maintain records of all *Bt* corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed.

7] Beginning on January 31, 2004 and annually thereafter, the registrant shall provide EPA with a report showing the number of units of its *Bt* MON863 corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve-month period covering the prior August through July.

8] The registrant must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

c. IRM Education and IRM Compliance Monitoring Programs

1] Monsanto must design and implement a comprehensive, ongoing IRM education program designed to convey to *Bt* MON863 corn users the importance of complying with the IRM program. The program shall include information encouraging *Bt* MON863 corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to *Bt* MON863 corn fields. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, EPA reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials. Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each *Bt* MON863 corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Monsanto shall coordinate its education programs with educational efforts of other registrants and other organizations, such as the National Corn Growers Association and state extension programs.

2] Annually, the registrant shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraph 6] and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3] Beginning January 31, 2004 and annually thereafter, the registrants must provide a report to EPA summarizing the activities carried out under the education program for the prior year and the plans for

their education program during the current year. The registrant must either submit a separate report or contribute to the report from the industry working group (ABSTC).

4] The registrant must design and implement an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing its MON863 *Bt* corn product are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to the MON863 *Bt* corn product. The registrant shall coordinate with other *Bt* corn registrants in designing and implementing its compliance assurance program and integrate the Cry3Bb1 CAP with the CAP already approved for MON810, EPA Registration Number 524-489. The registrant must prepare and submit within 90 days of the date of registration a written description of their compliance assurance program including a summary of the program implemented in the 2003 growing season. Other required features of the program are described in paragraphs 5] - 15] below.

5] The registrant must establish and publicize a "phased compliance approach," i.e., a guidance document that indicates how the registrant will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers. The options shall include withdrawal of the right to purchase MON863 *Bt* corn for an individual grower or for all growers in a specific region. An individual grower found to be significantly out of compliance two years in a row would be denied sales of the product the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell MON863 *Bt* corn.

6] The IRM compliance assurance program shall include an annual survey of a statistically representative sample of *Bt* corn growers conducted by an independent third party. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from the independent marketing research firm and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the U.S.

7] The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.

8] The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.

9] The registrant shall provide a preliminary summary of their findings by November 15 and a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA by January 31 of each year. The registrant shall confer with EPA on the design and content of the survey prior to its implementation.

10] Annually, the registrant shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey required under paragraphs 6] through 8] and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. The registrants must confer with the Agency prior to adopting any changes to a previously approved CAP.

11] The registrant shall train its representatives who make on-farm visits with MON863 *Bt* corn growers to perform assessments of compliance with IRM requirements. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.

12] The registrant shall carry out a program for investigating legitimate "tips and complaints" that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach."

13] If a grower, who purchases MON863 *Bt* corn for planting, was specifically identified as not being in compliance during the previous year, the registrant shall visit with the grower and evaluate whether that the grower is in compliance with the IRM program for the current year.

14] Beginning January 31, 2004 and annually thereafter, Monsanto shall provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken.

15] The registrant and the seed corn dealers for the registrant must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license number of the growers will be protected.

d. Insect Resistance Monitoring

The Agency is imposing the following conditions for this product:

1) The registrants will monitor for resistance and/or trends in increased tolerance for corn rootworm. Sampling should be focused in those areas in which there is the highest risk of resistance development. You must submit a protocol within 90 days of the date of registration.

2) The registrant shall provide to EPA a description of its resistance monitoring plan by January 31, 2004. The description shall include: sampling (number of locations and samples per locations), sampling methodology, bioassay methodology, standardization procedures, detection technique and sensitivity, and the statistical analysis of the probability of detecting resistance.

3) The registrant must follow up on grower, extension specialist or consultant reports of less than expected results or control failures for the corn rootworm. The registrant will instruct its customers (growers and seed distributors) to contact them (e.g., via a toll-free customer service number) if incidents of unexpected levels of damage occurs from these target pests. The registrant will investigate all damage reports submitted to the company or the company's representatives. See Remedial Action Plans section below.

5) A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by April 30th each year for the duration of the conditional registration.

e. Remedial Action Plans

A Remedial Action Plan covering both suspected and confirmed resistance for corn rootworm must be submitted by 1/31/2004. If resistance is confirmed, all MON863 acres (MON863 Bt fields and non-MON863 Bt refuges) must be treated with insecticides targeted at CRW adults as well as larvae.

Annual Reports:

The registrant will provide an annual reports to EPA on its Cry3Bb1 PIP expressed in corn based on the following table.

Report	Description	Due Date
Annual Sales	Reported by county and state summed by state	January 31 st each year beginning in 2004
Grower Agreement	Number of units of <i>Bt</i> corn seeds shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements	January 31 st each year beginning in 2004
Grower Education	Education program completed previous year and plan for next year	January 31 st each year beginning in 2004
Proposed Compliance Plan	Written description of Compliance Assurance Program	90 Days of the Date of Registration
Compliance Assurance Plan	Compliance Assurance Program Activities and Results	January 31 st each year starting in 2004
Compliance	To include annual survey results and plans for the next year	Preliminary survey report November 15 th each year and full report January 31 st each year thereafter
Insect Resistance Monitoring	Submission of protocol	90 Days of the Date of Registration
Insect Resistance Monitoring	Description of the program including sampling (number of locations and samples per locations), sampling methodology, bioassay methodology, standardization procedures, detection technique and sensitivity, and the statistical analysis of the probability of detecting resistance.	January 31, 2004

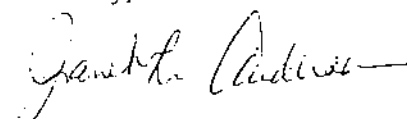
Additional reports are due as described in the following table:

IRM Grower Agreements	Proposed system to assure growers sign grower agreements	90 Days of the Date of Registration
IRM Affirmation Plan	System to assure annual affirmation by growers of their IRM obligations	90 Days of the Date of Registration
Changes to Grower Agreement and/or IRM documents	Current grower agreement(s) and any specific stewardship documents	At least 30 days before any changes related to IRM are expected to be imposed.
Insect Resistance Monitoring Results	Results of monitoring and investigations of damage reports	April 30 th each year

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,



Janet L. Andersen, Ph.D, Director
Biopesticides and Pollution
Prevention Division (7511C)

Enclosure

Corn Event MON 863: Rootworm Protected Corn

[Alternate brand name: *YieldGard® Rootworm: Rootworm Protection*]

This product is effective in controlling damage caused by corn rootworm larval feeding on corn roots.

Active Ingredient:

Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary for its production (ZMIR13L) in event MON 863 corn.....0.001 - 0.006%

Other Ingredients:

Substance produced by a marker gene and the genetic material necessary for its production (ZMIR13L) in event MON 863 corn.....0.00002 - 0.00003%

Percentage (wt/wt) on a dry weight basis.

Keep Out of Reach of Children

CAUTION

® YieldGard is a trademark of Monsanto Technology LLC

EPA Registration No. 524-528

EPA Establishment No. 524-MO-002

©2003 Monsanto Company
700 Chesterfield Parkway West
St. Louis, MO 63017

1 ACCEPTED
FOR COMMERCIAL
USE IN EPA REG. NO. 524-528
Feb 24, 2002
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, this product is
registered under EPA Reg. No.
524-528

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling.

The following information regarding commercial production must be included in the Event MON 863 Technology Use Guide.

Insect Resistance Management

Growers of Corn Event MON 863: Rootworm Protected Corn must adhere to the following refuge requirements. Growers must plant a structured refuge of at least 20% non-Event MON 863 corn.

Refuge planting options include: adjacent blocks or in-field strips. If blocks are implemented they must be adjacent to the Corn Event MON 863 field. If in-field strips within a corn field are implemented, then at least 6, and preferably 12 consecutive rows should be planted with non-event MON 863 corn.

The refuge and Corn Event MON 863 acres should be managed under comparable agronomic regimes. Refuge and Corn Event MON 863 acres should both be irrigated if irrigation is used. In regions where corn is cropped continuously, refuge and Corn Event MON 863 acres should be planted in a continuous cropping regime. The refuge may be placed only on first-year corn acres if the Event MON 863 corn is planted on first-year corn acres.

Growers have the option of applying conventional insecticides to the corn refuge for control of corn rootworm larvae. Growers are not permitted to apply agents for control of adult corn rootworm to the refuge as this would render the refuge less effective. If growers opt to treat for other insects present in the refuge while adult corn rootworm are present, then the Corn Event MON 863 acres must be treated in a like manner.

These refuge requirements do not apply to operations engaged in the propagation of inbred seed corn.

Corn Insects Controlled or Suppressed

Corn has been genetically transformed to produce the *B.t.* protein, Cry3Bb1, for control or suppression of the following coleopteran insects:

Western corn rootworm (*Diabrotica virgifera virgifera*)

Northern corn rootworm (*Diabrotica barberi*)

Mexican corn rootworm (*Diabrotica virgifera zea*)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511C)
1200 Pennsylvania Avenue NW
Washington, DC 20460

EPA Reg. Number:

524-528

Date of Issuance:

Feb 24, 2003

Term of Issuance:

Conditional

Name of Pesticide Product:

Corn Event MON863

NOTICE OF PESTICIDE:

 X Registration
 Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Monsanto Company
700 Chesterfield Parkway West
St. Louis, MO 63017

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

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- 1) The subject registration will automatically expire on midnight May 1, 2004. The registration must expire on this date because this is the date of expiration of the tolerance exemption under 40 CFR 180.1214. When and if the Agency registers this product, it is our understanding that Monsanto intends to submit in the near future an amendment application to modify the expiration date and a petition to amend the tolerance exemption under 40 CFR 180.1214 so that its expiration date is removed. Based on the Agency's review of the data submitted and cited in support of this application, and provided that the Agency finalizes a rule which amends 40 CFR 180.1214 so that its expiration date is removed; the Agency anticipates at this time that an expiration date three years from the initial date of registration for this product would be appropriate.
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- 3) Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires registrants of similar products to submit such data.

Signature of Approving Official:

[Signature]

CONCURRENCES

Date:

Feb 24, 2003

SYMBOL	EPA Form 8570-6						
SURNAME							
DATE							

4) Submit production information for this product to Mr. Owen Decker, Office of Pesticide Programs, Registration Division (mail code 7505C) for the fiscal year in which this product is conditionally registered, in accordance with FIFRA § 29. The fiscal year begins October 1 and ends September 30. Production information will be submitted to the Agency no later than December 15, following the end of the preceding fiscal year.

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8) Submit laboratory toxicity tests with *Orius insidiosus* (minute pirate bug), carabid (ground beetle), and *Tetraopes* (red milkweed beetle) within 24 months of the date of registration, provided the registration is amended to extend the registration date. Protocols are due within 120 days of the date of registration.

9) Full-scale field or semi-field studies with appropriate end points and statistical power must be conducted. Submit intermediate and multi-year non-target organism field studies with statistical power. You must submit final results to field studies previously summarized in MRID No.456530-03 (the carabid and nematode data are of particular interest) and annual reports each year of this registration every April 30th.

10) Submit a six week broiler dietary study with 60% - 70% MON 863 corn in the diet that is of appropriate duration to represent the start and end of the life cycle of the test species. Balanced diets should be formulated according to the National Research Council guidelines (Nutrient Requirements of

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Poultry," Ninth Revised Edition, 1994) with the energy requirements of the test species being met by the inclusion of corn in the diet to assess hazards from chronic exposure of wild or domesticated fowl. A protocol for poultry studies must be submitted within 90 days of the date of registration with a final report submitted 18 months after approval of the protocol.

11) Submit the following insect resistance management/pest biology data. Protocols and data sets identified in Monsanto's 12/13/2002 letter must be submitted within 90 days of the date of registration. A progress report must be submitted by January 31, 2004. Provided the registration is amended to extend the expiration date, the final reports must be submitted by January 31, 2006.

- Research regarding adult and larval movement and dispersal, mating habits, ovipositional patterns, number of times a female can mate and fecundity.
- Research to determine if IRM strategies designed for WCRW and NCRW are appropriate for MCRW
- Research regarding the mechanism of potential resistance of CRW to MON 863 is necessary to develop an appropriate long-term IRM strategy. Monsanto must attempt to develop resistant CRW colonies to aid in determining selection intensity.
- Research regarding the effect of WCRW ovipositing in soybean prior to overwintering and extended diapause in NCRW on an IRM strategy needs further investigation.
- Detailed summaries of the four data-sets identified in Monsanto's December 13, 2002 letter should be submitted to the Agency to support their conclusion that the initial resistance allele frequency is ≤ 0.01 .
- Baseline susceptibility studies currently underway should be continued for WCRW and initiated for NCRW and monitoring techniques such as discriminating dose concentration assays need to be thoroughly investigated for their feasibility as resistance monitoring tools.

12) BPPD strongly urges Monsanto to submit data and information cited in the benefits assessment (contained in the MON863 Biopesticides Regulatory Action Document) to help measure the impacts and potential benefits of the use of MON 863 corn on a wide scale. [Note that this is not a required term or condition of the registration.]

13) You must implement the following Insect Resistance Management Program:

The required IRM program for Cry3Bb1 Bt corn has the following elements:

- 1) Requirements relating to creation of a non-Cry3Bb1 Bt corn refuge in conjunction with the planting of any acreage of commercial Cry3Bb1 Bt corn;
- 2) Requirements for the registrants to prepare and require Cry3Bb1 Bt corn users to sign "grower agreements" which impose binding contractual obligations on the grower to comply with the refuge requirements;

3) Requirements for the registrants to develop compliance and report to EPA on programs to educate growers about IRM requirements;							
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4] Requirements for the registrants to develop, implement, and report to EPA on programs to evaluate and promote growers' compliance with IRM requirements (the Cry3Bb1 Compliance Assurance Program (CAP) must integrate with the CAP already approved for MON810, EPA Registration Number 524-489);

5] Requirements for the registrants to develop, implement, and report to EPA on monitoring programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry3Bb1 protein in the target insects;

6] Requirements for the registrants to develop, and if triggered, to implement a "remedial action plan" which would contain measures the registrants would take in the event that any insect resistance was detected as well as to report on activity under the plan to EPA;

7] Submit annual reports on sales (by state and county), IRM grower agreements results, compliance, and educational program on or before January 31st each year beginning in 2004.

a. Refuge Requirements

Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- Specifically, growers must plant a structured refuge of at least 20% non-Cry3Bb1 *Bt* corn that may be treated with insecticides as needed to control corn rootworm larvae. Growers will not be permitted to apply CRW labeled insecticides to the refuge for control of insect pests while adult corn rootworm are present unless the Cry3Bb1 field is treated in a similar manner.
- Refuge planting options include: refuge acres should be planted as blocks adjacent to MON 863 corn fields or as in-field strips.
- External refuges must be planted adjacent to Cry3Bb1 MON 863 fields.
- When planting the refuge in strips across the field, refuges must be at least 6 rows wide, preferably 12 consecutive rows wide.
- Insecticide treatments for control of corn rootworm larvae may be applied. Instructions to growers will specify that insecticides labeled for control of corn rootworm adults cannot be applied while adults are present in the refuge unless the Cry3Bb1 field is treated in a similar manner.

b. Grower Agreements

1] Persons purchasing the *Bt* corn product must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.

2] The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.

3] The registrant must develop a system (equipment) to ensure that the CAP is already approved for MON 810, EPA Reg. No. 524-489) which is reasonably likely to assure that persons purchasing the *Bt* corn product will affirm

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annually that they are contractually bound to comply with the requirements of the IRM program. The proposed system will be submitted to EPA within 90 days from the date of registration.

4] The registrant must use grower agreements and submit to EPA within 90 days from the date of registration a copy of that agreement and any specific stewardship documents referenced in the grower agreement. If Monsanto wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty days prior to implementing a proposed change, the registrant must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of the amendment.

5] The registrant must establish a system (equivalent to what is already approved for MON 810, EPA Reg. No. 524-489) which is reasonably likely to assure that persons purchasing the *Bt* corn sign grower agreement(s), and must provide within 90 days from the date of the registration a written description of that system.

6] The registrant shall maintain records of all *Bt* corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed.

7] Beginning on January 31, 2004 and annually thereafter, the registrant shall provide EPA with a report showing the number of units of its *Bt* MON863 corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve-month period covering the prior August through July.

8] The registrant must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

c. IRM Education and IRM Compliance Monitoring Programs

1] Monsanto must design and implement a comprehensive, ongoing IRM education program designed to convey to *Bt* MON863 corn users the importance of complying with the IRM program. The program shall include information encouraging *Bt* MON863 corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to *Bt* MON863 corn fields. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, EPA reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials. Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each *Bt* MON863 corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Monsanto shall coordinate its education programs with educational efforts of other registrants and other organizations, such as the National Corn Growers Association and state extension programs.

2] Annually, the registrant shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraph 6] and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3] Beginning January 31, 2004 and annually thereafter, registrants must provide a report to EPA summarizing the activities carried out under the education program for the prior year and the plans for					
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their education program during the current year. The registrant must either submit a separate report or contribute to the report from the industry working group (ABSTC).

4) The registrant must design and implement an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing its MON863 *Bt* corn product are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to the MON863 *Bt* corn product. The registrant shall coordinate with other *Bt* corn registrants in designing and implementing its compliance assurance program and integrate the Cry3Bb1 CAP with the CAP already approved for MON810, EPA Registration Number 524-489. The registrant must prepare and submit within 90 days of the date of registration a written description of their compliance assurance program including a summary of the program implemented in the 2003 growing season. Other required features of the program are described in paragraphs 5) - 15) below.

5) The registrant must establish and publicize a "phased compliance approach," i.e., a guidance document that indicates how the registrant will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers. The options shall include withdrawal of the right to purchase MON863 *Bt* corn for an individual grower or for all growers in a specific region. An individual grower found to be significantly out of compliance two years in a row would be denied sales of the product the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell MON863 *Bt* corn.

6) The IRM compliance assurance program shall include an annual survey of a statistically representative sample of *Bt* corn growers conducted by an independent third party. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from the independent marketing research firm and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the U.S.

7) The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.

8) The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.

9) The registrant shall provide a preliminary summary of their findings by November 15 and a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA by January 31 of each year. The registrant shall confer with EPA on the design and content of the survey prior to its implementation.

10) Annually, the registrant shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey required under paragraphs 6) through 8) and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. The registrants must confer with the Agency prior to adopting any changes to a

previously approved CAP		CONCURRENCES					
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11] The registrant shall train its representatives who make on-farm visits with MON863 *Bt* corn growers to perform assessments of compliance with IRM requirements. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.

12] The registrant shall carry out a program for investigating legitimate "tips and complaints" that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach."

13] If a grower, who purchases MON863 *Bt* corn for planting, was specifically identified as not being in compliance during the previous year, the registrant shall visit with the grower and evaluate whether that the grower is in compliance with the IRM program for the current year.

14] Beginning January 31, 2004 and annually thereafter, Monsanto shall provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken.

15] The registrant and the seed corn dealers for the registrant must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license number of the growers will be protected.

d. Insect Resistance Monitoring

The Agency is imposing the following conditions for this product:

- 1) The registrants will monitor for resistance and/or trends in increased tolerance for corn rootworm. Sampling should be focused in those areas in which there is the highest risk of resistance development. You must submit a protocol within 90 days of the date of registration.
- 2) The registrant shall provide to EPA a description of its resistance monitoring plan by January 31, 2004. The description shall include: sampling (number of locations and samples per locations), sampling methodology, bioassay methodology, standardization procedures, detection technique and sensitivity, and the statistical analysis of the probability of detecting resistance.
- 3) The registrant must follow up on grower, extension specialist or consultant reports of less than expected results or control failures for the corn rootworm. The registrant will instruct its customers (growers and seed distributors) to contact them (e.g., via a toll-free customer service number) if incidents of unexpected levels of damage occurs from these target pests. The registrant will investigate all damage reports submitted to the company or the company's representatives. See Remedial Action Plans section below.

5) A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by April 30th each year for the duration of the conditional registration.

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A Remedial Action Plan covering both suspected and confirmed resistance for corn rootworm must be submitted by 1/31/2004. If resistance is confirmed, all MON863 acres (MON863 Bt fields and non-MON863 Bt refuges) must be treated with insecticides targeted at CRW adults as well as larvae.

Annual Reports:

The registrant will provide an annual reports to EPA on its Cry3Bb1 PIP expressed in corn based on the following table.

Report	Description	Due Date
Annual Sales	Reported by county and state summed by state	January 31 st each year beginning in 2004
Grower Agreement	Number of units of <i>Bt</i> corn seeds shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements	January 31 st each year beginning in 2004
Grower Education	Education program completed previous year and plan for next year	January 31 st each year beginning in 2004
Proposed Compliance Plan	Written description of Compliance Assurance Program	90 Days of the Date of Registration
Compliance Assurance Plan	Compliance Assurance Program Activities and Results	January 31 st each year starting in 2004
Compliance	To include annual survey results and plans for the next year	Preliminary survey report November 15 th each year and full report January 31 st each year thereafter
Insect Resistance Monitoring	Submission of protocol	90 Days of the Date of Registration
Insect Resistance Monitoring	Description of the program including sampling (number of locations and samples per locations), sampling methodology, bioassay methodology, standardization procedures, detection technique and sensitivity, and the statistical analysis of the probability of detecting resistance.	January 31, 2004

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

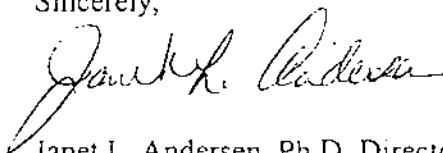
Additional reports are due as described in the following table:

IRM Grower Agreements	Proposed system to assure growers sign grower agreements	90 Days of the Date of Registration
IRM Affirmation Plan	System to assure annual affirmation by growers of their IRM obligations	90 Days of the Date of Registration
Changes to Grower Agreement and/or IRM documents	Current grower agreement(s) and any specific stewardship documents	At least 30 days before any changes related to IRM are expected to be imposed.
Insect Resistance Monitoring Results	Results of monitoring and investigations of damage reports	April 30 th each year

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,



Janet L. Andersen, Ph.D, Director
Biopesticides and Pollution
Prevention Division (7511C)

Enclosure

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 24 2003

MEMORANDUM

SUBJECT: Consideration of Section 3(c)(7)(C) Conditional Registrations for the Monsanto Company *Bt* Corn Plant-Incorporated Protectant *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Material Necessary for its Production (Vector ZMIR13L) in Event MON863 Corn: (EPA File Symbol 524-LEI)

-DECISION MEMORANDUM-

FROM: Janet L. Andersen, Ph.D., Director
Biopesticides and Pollution Prevention Division

TO: James J. Jones, Deputy Director
Office of Pesticide Programs

I. ISSUE

Should the Agency conditionally register Monsanto Company's *Bt* corn product pursuant to FIFRA §3(c)(7)(C)?

II. BACKGROUND

Active Ingredient

Cry3Bb1 protein is a delta-endotoxin from *Bacillus thuringiensis* spp. *kumamotoensis* and has activity against certain beetles. The wild-type *cry3Bb1* gene was modified to enhance the protein's activity against the corn root worm complex.

EUPs and Tolerance Exemption

Several experimental use permits and amendment/extensions have been granted by the Agency since April 2000 for different Cry3Bb1 corn plant-incorporated protectants, EPA EUP Numbers 524-EUP-90, -92, and -93. A tolerance exemption was established for *Bacillus thuringiensis* Cry3Bb1 protein and the genetic material for its production in corn on May 11, 2001. This

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tolerance exemption was codified under 40 CFR Part 180.1214 and expires on May 1, 2004. Monsanto has indicated their intent to submit a petition amending the Cry3Bb1 corn tolerance exemption to remove the expiration date once they obtain commercial approval.

Registration Application and Public Comments

On March 1, 2001, EPA announced receipt of Monsanto's Event MON863 Cry3Bb1 corn seed increase registration application (EPA File Symbol 524-LEI) pursuant to the provisions of section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (66 FR 15435). On March 13, 2002, EPA announced receipt of a revised application from Monsanto for EPA File Symbol 524-LEI for full commercial use. Finally, on July 24, 2002, EPA announced a meeting of the FIFRA Scientific Advisory Panel (SAP) to consider and review corn rootworm plant-incorporated protectant insect resistance management and non-target insect issues (67 FR 48461).

Approximately 937 comments were received by EPA in response to these announcements. Comments were received from private citizens, independent farmers, farm cooperatives, farm industry representatives, trade organizations, advocacy groups, academic researchers, and government officials. Comments received included handwritten letters, typed letters, e-mails, faxes, and slide presentations from the SAP meeting.

Several organizations interested in the registration of MON 863 sponsored letter writing campaigns to promote their interests and provided form letters for members or other interested citizens to submit to EPA. Six master form letters were identified. The originating organizations for these campaign letters were not apparent, and the master letters were identified on the basis of the most consistently copied text. Most of the 937 comments received were form letters (81 percent). In some cases the form letters were signed and mailed without alteration. However, many commenters added personalized comments or edited the form letters to better express their individual views.

About 88 percent of the 937 comments were received from private citizens. Support or opposition of the registration was not tracked for individual commenters; however, all six of the master form letters expressed support for the registration of MON 863. Based on the large number of form letters received and the large number of letters received from private citizens, most of the private citizens who commented on the application generally support registration.

Some of the major environmental or public interest groups included the Center for Science in Public Interest, Foundation E.A.R.T.H., Greenpeace, The Sierra Club, The Xerces Society, and Union of Concerned Scientists. The Center for Science in Public Interest did not express strong support or opposition to the registration of MON 863, but did provide a detailed analysis identifying perceived flaws in the Insect Resistance Management (IRM) plan. Foundation E.A.R.T.H., an environmental organization focusing on agriculture, supported approval of the registration based on an impact survey of 300 corn growers who, by and large, were interested in reducing pesticide use and using a seed product like MON 863. Greenpeace, The Sierra Club,

and The Xerces Society, all environmental advocacy groups, along with the Union of Concerned Scientists, a public interest group, opposed approval of the application claiming that insufficient scientific data are available. Each of these groups provided lengthy comments and/or independent evaluations of the application materials submitted by Monsanto.

Agricultural trade associations generally supported approval of registration of MON 863. Among these trade associations were the American Seed Trade Association, the Agribusiness Association of Iowa, the Illinois Corn Growers Association, the Iowa Corn Growers Association, the Nebraska Corn Growers Association, the Iowa Seed Association, the National Grain and Feed Association, and the National Wild Turkey Federation. A representative of the National Corn Growers Association supported the registration and expressed the importance of a workable IRM plan. The Illinois Corn Growers Association expressed concerns about handling and marketing the product.

Approximately 20 seed and grain companies submitted comments in support of registration of MON 863. Entomologists from research and academic organizations including the NCR-46 committee (a technical committee of research and extension entomologists), Iowa State University, Kansas State University, Michigan State University, Pennsylvania State University, and the University of Delaware also expressed support of the registration. Government representatives of the Illinois Department of Agriculture, Illinois State Senate, Iowa Department of Agriculture, Nebraska Department of Agriculture, Ohio Department of Agriculture, Texas House of Representatives, Texas Senate, and U.S. Department of Agriculture all supported registration of MON 863.

BPPD will do a separate response to comment document that will be available at the time the registration decision is announced in the Federal Register. We anticipate this will be within approximately 30 days.

III. RATIONALE FOR RECOMMENDATION

Pursuant to FIFRA section 3(c)(7)(C), EPA may conditionally register a new pesticide active ingredient for a period of time reasonably sufficient for the generation and submission of required data that are lacking because insufficient time has elapsed since the imposition of the data requirement for those data to be developed. EPA may grant such conditional registration only if EPA determines that (1) the use of the pesticide product during the period of the conditional registration will not cause any unreasonable adverse effect on the environment, and (2) the registration and use of the pesticide during the conditional registration is in the public interest. BPPD determines that all of the relevant criteria have been fulfilled.

BPPD determines that it is appropriate to conditionally register the MON 863 product under Section 3(c)(7)(C) because insufficient time has elapsed since the imposition of the data requirements for:

- 1) Independent laboratory analytical method validation.
- 2) Cry3Bb1 protein expression data in terms of dry weight, as the amount of protein present in the given tissue.
- 3) Field degradation studies evaluating accumulation and persistence of Cry3Bb1 protein in several different soils in various strata.
- 4) Laboratory toxicity test with *Orius insidiosus* (minute pirate bug).
- 5) Laboratory toxicity test with carabid (ground beetle).
- 6) Laboratory toxicity test with *Tetraopes* (red milkweed beetle).
- 7) Intermediate and multi-year non-target organism field studies with statistical power.
- 8) A six week broiler dietary study.
- 9) Research regarding corn rootworm adult and larval movement and dispersal, mating habits, ovipositional patterns, number of times a female can mate and fecundity.
- 10) Research to determine if IRM strategies designed for WCRW and NCRW are appropriate for MCRW.
- 11) Research regarding the mechanism of potential resistance of CRW to MON 863. Monsanto must attempt to develop resistant CRW colonies to aid in determining selection intensity.
- 12) Research regarding the effect of WCRW ovipositing in soybean prior to overwintering and extended diapause in NCRW on an IRM strategy.
- 13) Detailed summaries of the four data-sets identified in Monsanto's December 13, 2002 letter should be submitted to the Agency to support their conclusion that the initial resistance allele frequency is ≤ 0.01 .
- 14) Continuation of baseline susceptibility studies currently underway for WCRW and initiation for NCRW and monitoring techniques such as discriminating dose concentration assays, as well as investigation of their feasibility as resistance monitoring tools.

The applicant has submitted or cited data sufficient for BPPD to determine that conditional registration of MON 863 under FIFRA 3(c)(7)(C) will not result in unreasonable adverse effects to the environment, as discussed above. Monsanto Company submitted and/or cited satisfactory data pertaining to the proposed use. The human health effects data and non-target organism effects data are considered sufficient for the period of the conditional registration. These data demonstrate that no foreseeable human health hazards or ecological effects are likely to arise from the use of the product and that the risk of resistance developing to *Bacillus thuringiensis* Cry3Bb1 protein during the conditional registration is not expected to be significant. The data also demonstrate that there is virtually no possibility of any risk associated with weediness or outcrossing to wild relatives.

Registration of *Bacillus thuringiensis* Cry3bb1 protein and the genetic material necessary for its production (vector ZMIR3L) in event MON863 corn is in the public interest because MON 863 corn is less risky to human health and/or the environment than currently registered pesticides and the improved season long protection and practical benefits of ease of MON 863 use exceed those of the currently registered alternatives, most of which are restricted use products.— Specifically:

- 1) for the first 3 year, MON 863 is projected to reduce conventional pesticide use by 12.5 million lbs active ingredient on 7.5 million corn acres (0.1 carbamates, 3.5 pyrethroids, 3.0

organophosphates, and 0.9 for other chemical classes. This totals to 7.5 million acres of use reduction. To the extent that MON 863 is used on acreage that would be uneconomical to otherwise treat, the total use reduction would be less than the MON 863 acres adoption.)

2) it has a predicted yield benefit of 1.5 – 4.5% per acre greater than conventionally treated corn, 3) grower benefits are estimated at \$6.56 per acre vs. conventionally treated corn, 4) the total first 3 year economic benefits are estimated at \$49.2 million.

(EPA's public interest analysis considers three years of MON 863 use, because EPA has been informed that Monsanto will request that the current tolerance exemption for Cry 3bB1, which expires on May 1, 2004, be amended to remove the expiration date. If (1) Monsanto requests such an amendment to the Cry 3Bb1 tolerance exemption, (2) EPA grants such amendment request, and (3) Monsanto subsequently requests that the MON 863 registration be amended to expire at a later date, EPA currently believes that the data reviewed so far likely will support an extension of the conditional registration for an additional two years.)

In view of these minimal risks and the clear benefits related to YieldGard Rootworm, BPPD believes that the use of the product during the limited period of the conditional registration will not cause any unreasonable adverse effects.

Although the data with respect to this particular new active ingredient are satisfactory, they are not sufficient to support an unconditional registration under FIFRA 3(c)(5). Additional data are necessary to evaluate the risk posed by the continued use of this product. Consequently, BPPD recommends imposing the data requirements specified earlier in the attached Biopesticide Registration Action Document in Section III.

BPPD also believes, as explained in the attached BRAD section II.E., that the third criterion for a FIFRA 3(c)(7)(C) conditional registration has been fulfilled because the use of Cry3Bb1 corn under this registration would be in the public interest.

A tolerance exemption has been granted pursuant to FFDCA section 408(d) for *Bacillus thuringiensis* Cry3Bb1 protein and the genetic material necessary for its production in corn. However, this tolerance exemption expires in May 2004 and therefore, this registration would also expire in May 2004 until such time as the tolerance is permanent. At that time, the registration would be amended to expire in three years from the date of the original registration.

IV. RECOMMENDATION

The submitted data in support of this registration under section 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) have been reviewed and determined to be adequate. Studies mentioned above are included in the terms, conditions, and limitations of this registration. This registration will not cause unreasonable adverse effects to man or the environment and is in the public interest.

Based on the data submitted and cited by the applicants and reviewed by BPPD staff, the Biopesticides and Pollution Prevention Division recommends that the Monsanto Company Cry3Bb1 corn product containing the new active ingredient *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Material Necessary for its Production (Vector ZMIR13L) in Event MON863 Corn be REGISTERED under FIFRA section 3(c)(7)(C), with appropriate limitations.

The expiration data of the registration has been set to match that of the tolerance exemption, May 1, 2004.

CONCUR: 

NONCONCUR: _____

DATE: 2/24/03

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB 24 2003

MEMORANDUM

SUBJECT: Consideration of Section 3(c)(7)(C) Conditional Registrations for the Monsanto Company *Bt* Corn Plant-Incorporated Protectant *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Material Necessary for its Production (Vector ZMIR13L) in Event MON863 Corn: (EPA File Symbol 524-LEI)

-DECISION MEMORANDUM-

FROM: Janet L. Andersen, Ph.D., Director
Biopesticides and Pollution Prevention Division

TO: James J. Jones, Deputy Director
Office of Pesticide Programs

I. ISSUE

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II. BACKGROUND

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EUPs and Tolerance Exemption

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

tolerance exemption was codified under 40 CFR Part 180.1214 and expires on May 1, 2004. Monsanto has indicated their intent to submit a petition amending the Cry3Bb1 corn tolerance exemption to remove the expiration date once they obtain commercial approval.

Registration Application and Public Comments

On March 1, 2001, EPA announced receipt of Monsanto's Event MON863 Cry3Bb1 corn seed increase registration application (EPA File Symbol 524-LEI) pursuant to the provisions of section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (66 FR 15435). On March 13, 2002, EPA announced receipt of a revised application from Monsanto for EPA File Symbol 524-LEI for full commercial use. Finally, on July 24, 2002, EPA announced a meeting of the FIFRA Scientific Advisory Panel (SAP) to consider and review corn rootworm plant-incorporated protectant insect resistance management and non-target insect issues (67 FR 48461).

Approximately 937 comments were received by EPA in response to these announcements. Comments were received from private citizens, independent farmers, farm cooperatives, farm industry representatives, trade organizations, advocacy groups, academic researchers, and government officials. Comments received included handwritten letters, typed letters, e-mails, faxes, and slide presentations from the SAP meeting.

Several organizations interested in the registration of MON 863 sponsored letter writing campaigns to promote their interests and provided form letters for members or other interested citizens to submit to EPA. Six master form letters were identified. The originating organizations for these campaign letters were not apparent, and the master letters were identified on the basis of the most consistently copied text. Most of the 937 comments received were form letters (81 percent). In some cases the form letters were signed and mailed without alteration. However, many commenters added personalized comments or edited the form letters to better express their individual views.

About 88 percent of the 937 comments were received from private citizens. Support or opposition of the registration was not tracked for individual commenters; however, all six of the master form letters expressed support for the registration of MON 863. Based on the large number of form letters received and the large number of letters received from private citizens, most of the private citizens who commented on the application generally support registration.

Some of the major environmental or public interest groups included the Center for Science in Public Interest, Foundation E.A.R.T.H., Greenpeace, The Sierra Club, The Xerces Society, and Union of Concerned Scientists. The Center for Science in Public Interest did not express strong support or opposition to the registration of MON 863, but did provide a detailed analysis identifying perceived flaws in the Insect Resistance Management (IRM) plan. Foundation E.A.R.T.H., an environmental organization focusing on agriculture, supported approval of the registration based on an impact survey of 300 corn growers who, by and large, were interested in reducing pesticide use and using a seed product like MON 863. Greenpeace, The Sierra Club,

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and The Xerces Society, all environmental advocacy groups, along with the Union of Concerned Scientists, a public interest group, opposed approval of the application claiming that insufficient scientific data are available. Each of these groups provided lengthy comments and/or independent evaluations of the application materials submitted by Monsanto.

Agricultural trade associations generally supported approval of registration of MON 863. Among these trade associations were the American Seed Trade Association, the Agribusiness Association of Iowa, the Illinois Corn Growers Association, the Iowa Corn Growers Association, the Nebraska Corn Growers Association, the Iowa Seed Association, the National Grain and Feed Association, and the National Wild Turkey Federation. A representative of the National Corn Growers Association supported the registration and expressed the importance of a workable IRM plan. The Illinois Corn Growers Association expressed concerns about handling and marketing the product.

Approximately 20 seed and grain companies submitted comments in support of registration of MON 863. Entomologists from research and academic organizations including the NCR-46 committee (a technical committee of research and extension entomologists), Iowa State University, Kansas State University, Michigan State University, Pennsylvania State University, and the University of Delaware also expressed support of the registration. Government representatives of the Illinois Department of Agriculture, Illinois State Senate, Iowa Department of Agriculture, Nebraska Department of Agriculture, Ohio Department of Agriculture, Texas House of Representatives, Texas Senate, and U.S. Department of Agriculture all supported registration of MON 863.

BPPD will do a separate response to comment document that will be available at the time the registration decision is announced in the Federal Register. We anticipate this will be within approximately 30 days.

III. RATIONALE FOR RECOMMENDATION

Pursuant to FIFRA section 3(c)(7)(C), EPA may conditionally register a new pesticide active ingredient for a period of time reasonably sufficient for the generation and submission of required data that are lacking because insufficient time has elapsed since the imposition of the data requirement for those data to be developed. EPA may grant such conditional registration only if EPA determines that (1) the use of the pesticide product during the period of the conditional registration will not cause any unreasonable adverse effect on the environment, and (2) the registration and use of the pesticide during the conditional registration is in the public interest. BPPD determines that all of the relevant criteria have been fulfilled.

BPPD determines that it is appropriate to conditionally register the MON 863 product under Section 3(c)(7)(C) because insufficient time has elapsed since the imposition of the data requirements for:

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- 1) Independent laboratory analytical method validation.
- 2) Cry3Bb1 protein expression data in terms of dry weight, as the amount of protein present in the given tissue.
- 3) Field degradation studies evaluating accumulation and persistence of Cry3Bb1 protein in several different soils in various strata.
- 4) Laboratory toxicity test with *Orius insidiosus* (minute pirate bug).
- 5) Laboratory toxicity test with carabid (ground beetle).
- 6) Laboratory toxicity test with *Tetraopes* (red milkweed beetle).
- 7) Intermediate and multi-year non-target organism field studies with statistical power.
- 8) A six week broiler dietary study.
- 9) Research regarding corn rootworm adult and larval movement and dispersal, mating habits, ovipositional patterns, number of times a female can mate and fecundity.
- 10) Research to determine if IRM strategies designed for WCRW and NCRW are appropriate for MCRW.
- 11) Research regarding the mechanism of potential resistance of CRW to MON 863. Monsanto must attempt to develop resistant CRW colonies to aid in determining selection intensity.
- 12) Research regarding the effect of WCRW ovipositing in soybean prior to overwintering and extended diapause in NCRW on an IRM strategy.
- 13) Detailed summaries of the four data-sets identified in Monsanto's December 13, 2002 letter should be submitted to the Agency to support their conclusion that the initial resistance allele frequency is ≤ 0.01 .
- 14) Continuation of baseline susceptibility studies currently underway for WCRW and initiation for NCRW and monitoring techniques such as discriminating dose concentration assays, as well as investigation of their feasibility as resistance monitoring tools.

The applicant has submitted or cited data sufficient for BPPD to determine that conditional registration of MON 863 under FIFRA 3(c)(7)(C) will not result in unreasonable adverse effects to the environment, as discussed above. Monsanto Company submitted and/or cited satisfactory data pertaining to the proposed use. The human health effects data and non-target organism effects data are considered sufficient for the period of the conditional registration. These data demonstrate that no foreseeable human health hazards or ecological effects are likely to arise from the use of the product and that the risk of resistance developing to *Bacillus thuringiensis* Cry3Bb1 protein during the conditional registration is not expected to be significant. The data also demonstrate that there is virtually no possibility of any risk associated with weediness or outcrossing to wild relatives.

Registration of *Bacillus thuringiensis* Cry3bb1 protein and the genetic material necessary for its production (vector ZMIR3L) in event MON863 corn is in the public interest because MON 863 corn is less risky to human health and/or the environment than currently registered pesticides and the improved season long protection and practical benefits of ease of MON 863 use exceed those of the currently registered alternatives, most of which are restricted use products.— Specifically:

- 1) for the first 3 year, MON 863 is projected to reduce conventional pesticide use by 12.5 million lbs active ingredient on 7.5 million corn acres (0.1 carbamates, 3.5 pyrethroids, 3.0

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organophosphates, and 0.9 for other chemical classes. This totals to 7.5 million acres of use reduction. To the extent that MON 863 is used on acreage that would be uneconomical to otherwise treat, the total use reduction would be less than the MON 863 acres adoption.)

2) it has a predicted yield benefit of 1.5 – 4.5% per acre greater than conventionally treated corn, 3) grower benefits are estimated at \$6.56 per acre vs. conventionally treated corn, 4) the total first 3 year economic benefits are estimated at \$49.2 million.

(EPA's public interest analysis considers three years of MON 863 use, because EPA has been informed that Monsanto will request that the current tolerance exemption for Cry 3bB1, which expires on May 1, 2004, be amended to remove the expiration date. If (1) Monsanto requests such an amendment to the Cry 3Bb1 tolerance exemption, (2) EPA grants such amendment request, and (3) Monsanto subsequently requests that the MON 863 registration be amended to expire at a later date, EPA currently believes that the data reviewed so far likely will support an extension of the conditional registration for an additional two years.)

In view of these minimal risks and the clear benefits related to YieldGard Rootworm, BPPD believes that the use of the product during the limited period of the conditional registration will not cause any unreasonable adverse effects.

Although the data with respect to this particular new active ingredient are satisfactory, they are not sufficient to support an unconditional registration under FIFRA 3(c)(5). Additional data are necessary to evaluate the risk posed by the continued use of this product. Consequently, BPPD recommends imposing the data requirements specified earlier in the attached Biopesticide Registration Action Document in Section III.

BPPD also believes, as explained in the attached BRAD section II.E., that the third criterion for a FIFRA 3(c)(7)(C) conditional registration has been fulfilled because the use of Cry3Bb1 corn under this registration would be in the public interest.

A tolerance exemption has been granted pursuant to FFDCA section 408(d) for *Bacillus thuringiensis* Cry3Bb1 protein and the genetic material necessary for its production in corn. However, this tolerance exemption expires in May 2004 and therefore, this registration would also expire in May 2004 until such time as the tolerance is permanent. At that time, the registration would be amended to expire in three years from the date of the original registration.

IV. RECOMMENDATION

The submitted data in support of this registration under section 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) have been reviewed and determined to be adequate. Studies mentioned above are included in the terms, conditions, and limitations of this registration. This registration will not cause unreasonable adverse effects to man or the environment and is in the public interest.

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Based on the data submitted and cited by the applicants and reviewed by BPPD staff, the Biopesticides and Pollution Prevention Division recommends that the Monsanto Company Cry3Bb1 corn product containing the new active ingredient *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Material Necessary for its Production (Vector ZMIR13L) in Event MON863 Corn be REGISTERED under FIFRA section 3(c)(7)(C), with appropriate limitations.

The expiration data of the registration has been set to match that of the tolerance exemption, May 1, 2004.

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NONCONCUR:

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

FEB 14 2003

Dr. Russell P. Schneider
Director, Regulatory Affairs
Monsanto Company
600 13th Street, N.W.
Suite 660
Washington, D.C. 20005

Dear Dr. Schneider:

Subject: MON863 Cry3Bb1 Corn/ Pre-Acceptance Letter
EPA File Symbol 524-LEI

This is a pre-acceptance letter regarding Monsanto's application to register the above referenced product for a Section 3 registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Environmental Protection Agency (EPA) will consider registering Monsanto's product under FIFRA Section 3(c)(7)(C) provided Monsanto amends its application for registration by submitting the required information as described in this letter.

This letter does not constitute a commitment to register the subject product, nor is it intended to imply that EPA will register the subject product. Rather, the purpose of this letter is to inform you that, if Monsanto submits the information in writing as described in this letter, EPA will be able to continue to process the registration application in accordance with our normal procedures.

Thus, to enable us to continue to process the subject registration application, EPA requests that Monsanto agree in writing to the following.

1) The subject registration will automatically expire on midnight May 1, 2004. The registration must expire on this date because this is the date of expiration of the tolerance exemption under 40 CFR 180.1214. When and if the Agency registers this product, it is our understanding that Monsanto intends to submit in the near future an amendment application to modify the expiration date and a petition to amend the tolerance exemption under 40 CFR 180.1214 so that its expiration date is removed. Based on the Agency's review of the data submitted and cited in support of this application, and provided that the Agency finalizes a rule which amends 40 CFR 180.1214 so that its expiration date is removed; the Agency anticipates at this time that an

expiration date three years from the initial date of registration for this product would be appropriate.

2) The subject registration will be limited to *Bacillus thuringiensis*-Cry3Bb1 Protein and the Genetic Material Necessary for its Production (Vector ZMIR13L) in Event MON863 Corn use in field corn.

3) Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires registrants of similar products to submit such data.

4) Submit production information for this product to Mr. Owen Beeder of Office of Pesticide Programs, Registration Division (mail code 7505C) for the fiscal year in which this product is conditionally registered, in accordance with FIFRA § 29. The fiscal year begins October 1 and ends September 30. Production information will be submitted to the Agency no later than December 15, following the end of the preceding fiscal year.

5) Submit independent laboratory method validation (under OPPTS Guidelines 860.1340) to complete the database for Cry3Bb1 corn within 12 months of the date of registration. Provide to the EPA laboratory (Ft. Meade, MD) methodology and/or reagents necessary for validation of a Cry3Bb1 analytical method within 6 months of the date of registration. The extraction and detection method as described for Cry3Bb1 protein appears to be adequate for analysis of Cry3Bb1 protein in corn grain. However, this method must be validated by both an independent laboratory and the EPA Biological and Economic Analysis Division laboratory before it can be considered a valid method. In addition, to assure that grain handlers have a test method in place prior to harvest, you must make available Cry3Bb1 strip tests to grain handlers and demonstrate to the Agency this provision prior to September 2003. EPA understands that these are 'qualitative' test kits and that you are in discussions with USDA/GIPSA about providing methodology and reagents for their use in developing a validated 'quantitative' method for MON 863 and that this transfer of materials will take place once registration occurs.

6) Submit expression data in terms of dry weight, as the amount of protein present in the given tissue. Tissues for which expression data must be provided include: leaf, root, pollen, seed, and whole plant. In addition, data for each of these tissues should be provided for young plants in rapid growth, during flowering, and mature plants before harvest when that part of the plant is present. Data obtained for roots should also include typical times when corn rootworm would be feeding. Data are due within 24 months of the date of registration, provided the registration is amended to extend the registration date.

7) Submit field degradation studies evaluating accumulation and persistence of Cry3Bb1 in several different soils in various strata. Representative fields must have been planted with MON863 and include both conventional tillage and no-till samples and be harvested under typical agronomic conditions. Sampling must continue until the limit of detection is reached. Studies should include soils with high levels of a variety of clays. Both ELISA and insect bioassays need to be conducted and compared to determine if Cry3Bb1 is accumulating or

persisting in soil samples. A protocol is due within 90 days of the date of registration, and a progress report is due within one year of the date of registration. If the registration and tolerance exemption are amended to extend the expiration dates, a final report is due two years from the date of registration.

8) Submit laboratory toxicity tests with *Orius insidiosus* (minute pirate bug), carabid (ground beetle), and *Tetraopes* (red milkweed beetle) within 24 months of the date of registration, provided the registration is amended to extend the registration date. Protocols are due within 120 days of the date of registration.

9) Full-scale field or semi-field studies with appropriate end points and statistical power must be conducted. Submit intermediate and multi-year non-target organism field studies with statistical power. You must submit final results to field studies previously summarized in MRID No.456530-03 (The carabid and nematode data are of particular interest.) and annual reports each year of this registration every April 30th.

10) Submit a six week broiler dietary study with 60% - 70% MON 863 corn in the diet that is of appropriate duration to represent the start and growing periods of the test species. Balanced diets should be formulated according to the National Research Council guidelines ("Nutrient Requirements of Poultry," Ninth Revised Edition, 1994) with the energy requirements of the test species being met by the inclusion of corn in the diet to assess hazards from chronic exposure of wild or domesticated fowl. A protocol for poultry studies must be submitted within 90 days of the date of registration with a final report submitted 18 months after approval of the protocol.

11) Submit the following insect resistance management/pest biology data. Protocols and data sets identified in Monsanto's 12/13/2002 letter must be submitted within 90 days of the date of registration. A progress report must be submitted by January 31, 2004. Provided the registration is amended to extend the expiration date, the final reports must be submitted by January 31, 2006.

- Research regarding adult and larval movement and dispersal, mating habits, ovipositional patterns, number of times a female can mate and fecundity.
- Research to determine if IRM strategies designed for WCRW and NCRW are appropriate for MCRW
- Research regarding the mechanism of potential resistance of CRW to MON 863 must be determined to develop an appropriate long-term IRM strategy. Monsanto must attempt to develop resistant CRW colonies to aid in determining selection intensity.
- Research regarding the effect of WCRW ovipositing in soybean prior to overwintering and extended diapause in NCRW on an IRM strategy needs further investigation.
- Detailed summaries of the four data-sets identified in Monsanto's December 13, 2002

letter should be submitted to the Agency to support their conclusion that the initial resistance allele frequency is ≤ 0.01 .

- Baseline susceptibility studies currently underway should be continued for WCRW and initiated for NCRW and monitoring techniques such as discriminating dose concentration assays need to be thoroughly investigated for their feasibility as resistance monitoring tools.

12) BPPD strongly urges Monsanto to submit data and information cited in the benefits assessment (contained in the MON863 Biopesticides Regulatory Action Document) to help measure the impacts and potential benefits of the use of MON 863 corn on a wide scale.

13) You must commit to do the following Insect Resistance Management Program:

The required IRM program for Cry3Bb1 *Bt* corn has the following elements:

- 1] Requirements relating to creation of a non-Cry3Bb1 *Bt* corn refuge in conjunction with the planting of any acreage of commercial Cry3Bb1 *Bt* corn;
- 2] Requirements for the registrants to prepare and require Cry3Bb1 *Bt* corn users to sign "grower agreements" which impose binding contractual obligations on the grower to comply with the refuge requirements;
- 3] Requirements for the registrants to develop, implement, and report to EPA on programs to educate growers about IRM requirements;
- 4] Requirements for the registrants to develop, implement, and report to EPA on programs to evaluate and promote growers' compliance with IRM requirements (the Cry3Bb1 Compliance Assurance Program (CAP) must integrate with the CryI CAP);
- 5] Requirements for the registrants to develop, implement, and report to EPA on monitoring programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry3Bb1 protein in the target insects;
- 6] Requirements for the registrants to develop, and if triggered, to implement a "remedial action plan" which would contain measures the registrants would take in the event that any insect resistance was detected as well as to report on activity under the plan to EPA;
- 7] Submit annual reports on sales (by state and county), IRM grower agreements results, compliance, and educational program on or before January 31st each year beginning in 2004.

a. Refuge Requirements

Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

- Specifically, growers must plant a structured refuge of at least 20% non-Cry3Bb1 *Bt* corn that may be treated with insecticides as needed to control corn rootworm larvae. Growers will not be permitted to apply CRW labeled insecticides to the refuge for control of insect pests while adult corn rootworm are present unless the Cry3Bb1 field is treated in a similar manner.
- Refuge planting options include: refuge acres should be planted as blocks adjacent to MON 863 corn fields or as in-field strips. If row strips within a corn field are implemented, then at least 6 and preferably 12 consecutive rows should be planted.
- External refuges must be planted adjacent to Cry3Bb1 MON 863 fields.
- When planting the refuge in strips across the field, refuges must be at least 6 rows wide, preferably 12 rows wide.
- Insecticide treatments for control of corn rootworm larvae may be applied. Instructions to growers will specify that insecticides labeled for control of corn rootworm adults cannot be applied while adults are present in the refuge unless the Cry3Bb1 field is treated in a similar manner.

b. Grower Agreements

1] Persons purchasing the *Bt* corn product must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.

2] The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.

3] The registrant must develop a system (equivalent to what is already approved for MON 810, EPA Reg. No. 524-489) which is reasonably likely to assure that persons purchasing the *Bt* corn product will affirm annually that they are contractually bound to comply with the requirements of the IRM program. The proposed system will be submitted to EPA within 90 days from the date of registration.

4] The registrant must use grower agreements and submit to EPA within 90 days from the date of registration a copy of that agreement and any specific stewardship documents referenced in the grower agreement. If Monsanto wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating

to the IRM program, thirty days prior to implementing a proposed change, the registrant must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of the amendment.

5] The registrant must establish a system (equivalent to what is already approved for MON 810, EPA Reg. No. 524-489) which is reasonably likely to assure that persons purchasing the *Bt* corn sign grower agreement(s), and must provide within 90 days from the date of the registration a written description of that system.

6] The registrant shall maintain records of all *Bt* corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed.

7] Beginning on January 31, 2004 and annually thereafter, the registrant shall provide EPA with a report showing the number of units of its *Bt* MON863 corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve-month period covering the prior August through July.

8] The registrant must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

c. IRM Education and IRM Compliance Monitoring Programs

1] Monsanto must design and implement a comprehensive, ongoing IRM education program designed to convey to *Bt* MON863 corn users the importance of complying with the IRM program. The program shall include information encouraging *Bt* MON863 corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to *Bt* MON863 corn fields. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, EPA reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials. Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each *Bt* MON863 corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Monsanto shall coordinate its education programs with educational efforts of other registrants and other organizations, such as the National Corn Grower Association and state extension programs.

2] Annually, the registrant shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraph 6] and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

- 3] Beginning January 31, 2004 and annually thereafter, the registrants must provide a report to EPA summarizing the activities carried out under the education program for the prior year and the plans for their education program during the current year. The registrant must either submit a separate report or contribute to the report from the industry working group (ABSTC).
- 4] The registrant must design and implement an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing its MON863 *Bt* corn product are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to the MON863 *Bt* corn product. The registrant shall coordinate with other *Bt* corn registrants in designing and implementing its compliance assurance program and integrate the Cry3Bb1 CAP with the Cry1 CAP. The registrant must prepare and submit within 90 days of the date of registration a written description of their compliance assurance program including a summary of the program implemented in the 2003 growing season. Other required features of the program are described in paragraphs 5] - 15] below.
- 5] The registrant must establish and publicize a "phased compliance approach," i.e., a guidance document that indicates how the registrant will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers. The options shall include withdrawal of the right to purchase MON863 *Bt* corn for an individual grower or for all growers in a specific region. An individual grower found to be significantly out of compliance two years in a row would be denied sales of the product the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell MON863 *Bt* corn.
- 6] The IRM compliance assurance program shall include an annual survey of a statistically representative sample of *Bt* corn growers conducted by an independent third party. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from the independent marketing research firm and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the U.S.
- 7] The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.
- 8] The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.
- 9] The registrant shall provide a preliminary summary of their findings by November 15 and a final written summary of the results of the prior year's survey (together with a description of the

regions, the methodology used, and the supporting data) to EPA by January 31 of each year. The registrant shall confer with EPA on the design and content of the survey prior to its implementation.

10] Annually, the registrant shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey required under paragraphs 6] through 8] and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. The registrants must confer with the Agency prior to adopting any changes.

11] The registrant shall train its representatives who make on-farm visits with MON863 *Bt* corn growers to perform assessments of compliance with IRM requirements. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.

12] The registrant shall carry out a program for investigating legitimate "tips and complaints" that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach."

13] If a grower, who purchases MON863 *Bt* corn for planting, was specifically identified as not being in compliance during the previous year, the registrant shall visit with the grower and evaluate whether that the grower is in compliance with the IRM program for the current year.

14] Beginning January 31, 2004 and annually thereafter, Monsanto shall provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken.

15] The registrant and the seed corn dealers for the registrant must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license number of the growers will be protected.

d. Insect Resistance Monitoring

The Agency is imposing the following conditions for this product:

1) The registrants will monitor for resistance and/or trends in increased tolerance for corn rootworm. Sampling should be focused in those areas in which there is the highest risk of

resistance development. You must submit a protocol within 90 days of the date of registration.

2) The registrant shall provide to EPA a description of its resistance monitoring plan by January 31, 2004. The description shall include: sampling (number of locations and samples per locations), sampling methodology, bioassay methodology, standardization procedures, detection technique and sensitivity, and the statistical analysis of the probability of detecting resistance.

3) The registrant must follow up on grower, extension specialist or consultant reports of less than expected results or control failures for the corn rootworm. The registrant will instruct its customers (growers and seed distributors) to contact them (e.g., via a toll-free customer service number) if incidents of unexpected levels of damage occurs from these target pests. The registrant will investigate all damage reports submitted to the company or the company's representatives. See Remedial Action Plans section below.

5) A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by April 30th each year for the duration of the conditional registration.

e. Remedial Action Plans

A Remedial Action Plan covering both suspected and confirmed resistance for corn rootworm must be submitted by 1/31/2004. If resistance is confirmed, all acres (MON863 Bt fields and non-Cry3Bb1 MON863 Bt refuges) should be treated with insecticides targeted at CRW adults as well as larvae.

Annual Reports:

The registrant will provide an annual reports to EPA on its Cry3Bb1 PIP expressed in corn based on the following table.

Report	Description	Due Date
Annual Sales	Reported by county and state summed by state	January 31 st each year beginning in 2004

Grower Agreement	Number of units of <i>Bt</i> corn seeds shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements	January 31 st each year beginning in 2004
Grower Education	Education program completed previous year and plan for next year	January 31 st each year beginning in 2004
Proposed Compliance Plan	Written description of Compliance Assurance Program	90 Days of the Date of Registration
Compliance Assurance Plan	Compliance Assurance Program Activities and Results	January 31 st each year starting in 2004
Compliance	To include annual survey results and plans for the next year	Preliminary survey report November 15 th each year and full report January 31 st each year thereafter
Insect Resistance Monitoring	Submission of protocol	90 Days of the Date of Registration
Insect Resistance Monitoring	Description of the program including sampling (number of locations and samples per locations), sampling methodology, bioassay methodology, standardization procedures, detection technique and sensitivity, and the statistical analysis of the probability of detecting resistance.	January 31, 2004

Additional reports are due as described in the following table:

IRM Grower Agreements	Proposed system to assure growers sign grower agreements	90 Days of the Date of Registration
-----------------------	--	-------------------------------------

IRM Affirmation Plan	System to assure annual affirmation by growers of their IRM obligations	90 Days of the Date of Registration
Changes to Grower Agreement and/or IRM documents	Current grower agreement(s) and any specific stewardship documents	At least 30 days before any changes related to IRM are expected to be imposed.
Insect Resistance Monitoring Results	Results of monitoring and investigations of damage reports	April 30 th each year

Label:

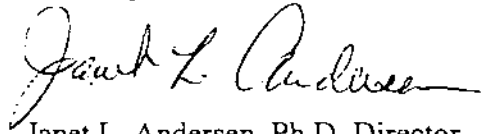
You must submit a revised label prior to further consideration of this registration application that includes the following statements.

The following information regarding commercial production must be included in the Grower Guide.

- Growers must plant a structured refuge of at least 20% non-Cry3Bb1 Bt corn that may be treated with insecticides as needed to control corn rootworm larvae. Growers will not be permitted to apply CRW labeled insecticides to the refuge for control of insect pests while adult corn rootworm are present unless the Cry3Bb1 field is treated in a similar manner.
- Refuge planting options include: refuge acres should be planted as blocks adjacent to MON 863 corn fields or as in-field strips. If row strips within a corn field are implemented, then at least 6 and preferably 12 consecutive rows should be planted.
- External refuges must be planted adjacent to Cry3Bb1 MON 863 fields.
- When planting the refuge in strips across the field, refuges must be at least 6 rows wide, preferably 12 rows wide.
- Insecticide treatments for control of corn rootworm larvae may be applied. Instructions to growers will specify that insecticides labeled for control of corn rootworm adults cannot be applied while adults are present in the refuge unless the Cry3Bb1 field is treated in a similar manner.

This letter does not mean that EPA agrees to amend the subject product. If Monsanto submits the information in writing as described in this letter, however, EPA will be able to continue to process the amendment application.

Sincerely,

A handwritten signature in cursive script, reading "Janet L. Andersen".

Janet L. Andersen, Ph.D, Director
Biopesticides and Pollution
Prevention Division (7511C)

Enclosure

MONSANTO



B

Dennis P. Ward, Ph.D.
Regulatory Affairs Manager
(636) 737-6631

MONSANTO COMPANY
600 13TH STREET, N.W.
SUITE 600
WASHINGTON, D.C. 20005
PHONE (202) 783-2460
FAX (202) 783-2468
<http://www.monsanto.com>

February 20, 2003

Document Processing Desk (APPL)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Attn: Phillip O. Hutton, Team Leader 90

Subj: Amendment to application for registration of Corn Event MON 863
EPA File Symbol 524-LEI

Dear Mr. Hutton:

In support of our application to register Corn Event MON 863 we are submitting a revised data matrix, label and Confidential Statement of Formula. Contained within the Data Matrix are numerous requests for data waivers. These waiver requests are based primarily on the low potential for exposure to Cry3Bb1 protein and the fact that many of microbial pesticide data requirements (49 CFR 158.740) are not applicable to a plant-incorporated protectant.

Enclosed with this submission are the following materials:

- Application for Pesticide (EPA Form 8570-1)
- Certification with Respect to Citation of Data (EPA Form 8570-34)
- Data Matrix (EPA Form 8570-35)
- Product label (5 copies)
- Confidential attachment

Except for the materials contained in the confidential attachment, Monsanto does not object to placement of materials contained in this submission in the Public Docket.

Should you require any additional information regarding this submission please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (636-737-6631).

Sincerely,

Dennis P. Ward, Ph.D.

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Mr. P. Hutton
2/20/2003
Page 2 of 45

Att: Administrative materials

cc: Mike Mendelsohn, EPA/OPP/BPPD
Russell Schneider, Monsanto

2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier
Number

Application for Pesticide – Section I

1. Company/Product Number File Symbol 524-LEI	2. EPA Product Manager Phillip O. Hutton	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
Company/Product (Name) Corn Event MON 863	PM # 90	
5. Name and Address of Applicant (Include ZIP Code) Monsanto Company 600 13 th St., N.W., Suite 660 Washington, DC 20005 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section – II

<input type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated
<input type="checkbox"/> Resubmission in response to Agency letter dated	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification – Explain below.	<input checked="" type="checkbox"/> Other – Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Submission of request for data waivers and revised data matrix, labeling and CSF in support of application to register Corn Event MON 863

Section – III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted	If "Yes" Unit Packaging wgt. No. per Container	If "Yes" Package wgt. No. per Container		<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other	(Specify)
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Other			
		<input type="checkbox"/> Paper glued			
		<input type="checkbox"/> Stenciled			

Section – IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Russell P. Schneider	Title Regulatory Affairs Director	Telephone No. (Include Area Code) (202) 383-2866
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>D. Ward</i>	3. Title Regulatory Affairs Manager	
4. Typed Name Dennis P. Ward Tel. (636) 737-6631	5. Date February 20, 2003	<i>48</i>



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401 M Street, S. W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number: Monsanto Company, 600 13 th Street, N.W., Washington, DC 2005 (202) 383-2866	EPA Registration Number / File Symbol: 524-LEI
Active Ingredient(s) and/or representative test compound(s): <i>B.t. Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn</i>	Date: February 20, 2003
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158: Terrestrial field crop	Product Name: Corn Event MON 863

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-in Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

Section I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies set offers of compensation (the Data Matrix Form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

Section II: GENERAL OFFER TO PAY

☐ (Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements) I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

Section III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-in response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under the applicable law.

Signature

Date

February 20, 2003

Typed or Printed Name and Title

Dennis P. Ward, Regulatory Affairs
Manager

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DATA MATRIX

Date: February 20, 2003		EPA Reg. No./File Symbol: 524-LEI		Page 1 of 14	
Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005		Product: Corn Event MON 863			
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151-20, 151-21, 151-25 885.1100 885.1200 885.1500	Administrative Materials for Amendment of Application to Registrant of a <i>Bacillus thuringiensis</i> Cry3Bb1 Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in Corn Event MON 863; EPA File Symbol LEI-524.	455770-00	Monsanto Company	OWN	Dated January 8, 2002
151-20, 153-4 885.1100 885.2200	Holleschak, G., R.E. Hileman and J.D. Astwood (2001). Immuno-detectability of NPTII Protein in the Grain of Insect Protected Corn Event MON 863 After Heat Treatment. MSL-17300.	455382-09	Monsanto Company	OWN	Dated November 5, 2001
151-20, 151-21, 151-22, 151-26 885.1100 885.1200 885.1300 885.2100	Cavato, T.A., E.C. Rigden, D.W. Miltanek and R.P. Lirette (2001). Amended Report for MSL-16505: Molecular Analysis of Corn Event MON 863. MSL-17152.	454240-02	Monsanto Company	OWN	Dated May 21, 2001
151-20, 153-4 885.1100 885.2200	Holleschak, G., R.E. Hileman and J.D. Astwood (2001). Amended Report for MSL-16597: Immunodetectability of Cry3Bb1.11098 and Cry3Bb1.11231 Proteins in the Grain of Insect Protected Corn Events MON 863 and MON 853 After Heat Treatment. MSL-17223.	454240-07	Monsanto Company	OWN	Dated May 21, 2001
151-23, 151-25, 153-4, 151-26, 885.1400, 885.1500 885.2200 885.2400 885.2500	Dudin, Y.A., B-P. Tonnu, L.D. Albee and R.P. Lirette (2001). Amended Report for MSL-16559: B.t. Cry3Bb1.11098 and NPTII Protein Levels in Sample Tissue Collected from Corn Event MON 863 Grown in 1999 Field Trials. MSL-171811.	454240-01	Monsanto Company	OWN	Dated May 21, 2001
Signature 			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.		Date February 20, 2003

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DATA MATRIX

Date: February 20, 2003		EPA Reg. No./File Symbol: 524-LEI		Page 2 of 14	
Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005		Product: Corn Event MON 863			
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151-26 885.2100	Administrative Materials in Support of the Registration of <i>Bacillus thuringiensis</i> Cry3Bb Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in Corn; and Amendment of the Previous Request for Exemption from the Requirement of a Tolerance, 10/27/1999	451568-00	Monsanto Company	OWN	Dated June 20, 2000
151-26 885.2100	Petition from the Requirement of a Tolerance for <i>Bacillus thuringiensis</i> Cry1, Cry2, and Cry3 Classes of Proteins and the Genetic Material Necessary for the Production of These Proteins in or On All Raw Agricultural Commodities When used as Plant-Pesticide Active Ingredients	PP 7F4888	Monsanto Company	OWN	Dated June 24, 1997
151-26 885.2100	Pilchinski, W. P. and M. W. Taylor (1999). Administrative Materials in Support of the Registration of the Plant-Expressed Protectant <i>Bacillus thuringiensis</i> Corn Rootworm Control Protein, as Produced in the Corn (<i>Zea mays</i> , L.), and the Amendment to the Previous Request for Exemption from the Requirement of a Tolerance	449043-00	Monsanto Company	OWN	Dated August 19, 1999
151-26 885.2100	Hileman, R.E. and J.D. Astwood (2001). Additional Characterization of the Cry3Bb1 Protein Produced in Corn Event MON 863. MSL-17137.	454240-10	Monsanto Company	OWN	Dated May 21, 2001
151-26 885.2100	Thoma, R.S., G. Holleschak, R.E. Hileman and J.D. Astwood (2001). Primary Structural Protein Characterization of Corn Event MON 863 Cry3Bb1.11098 Protein Using N-terminal Sequencing and MALDI Time of Flight Mass Spectrometric Techniques. MSL-1715.	454240-11	Monsanto Company	OWN	Dated May 21, 2001
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 20, 2003	

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DATA MATRIX

Date: February 20, 2003		EPA Reg. No./File Symbol: 524-LEI		Page 3 of 14	
Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005		Product: Corn Event MON 863			
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151-26 885.2100	Hileman, R.E., G. Holleschak, L.A. Turner, R.S. Thoma, C.R. Brown and J.D. Astwood (2001). Characterization and Equivalence of the Cry3Bb1 Protein Produced by <i>E. coli</i> Fermentation and Corn Event MON 863. MSL-17274.	455382-01	Monsanto Company	OWN	Dated November 5, 2001
151-25 885.2300	D. Kolwyck, B-P. Tonnu, Y. A. Dudin, T. Ploesser and K. Gustafson (2001). Validated Method for Extraction and Direct ELISA Analysis of Cry3Bb1 in Corn Grain.	453731-01	Monsanto Company	OWN	Dated April 7, 2001
151-27 885.2400	Samples will be submitted as part of the independent laboratory method validation work that is ongoing.				
153-4 885.2500	Dudin, Y.A., B-P. Tonnu, L.D. Albee and R.P. Lirette (2001). Amended Report for MSL-16559: <i>B.t.</i> Cry3Bb1.11098 and NPTII Protein Levels in Sample Tissue Collected from Corn Event MON 863 Grown in 1999 Field Trials. MSL-171811.	454240-01	Monsanto Company	OWN	Dated May 21, 2001
152-30 885.3050	Astwood, J.D., R.E. Hileman, M.J. McKee, T.J. Rydel, J.W. Seale and L. English (2001). Safety Assessment of Cry3Bb1 Variants in Corn Rootworm Protected Corn. MSL-17225. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	454240-09	Monsanto Company	OWN	Dated May 21, 2001
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 20, 2003	

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DATA MATRIX

Date: February 20, 2003

EPA Reg. No./File Symbol: 524-LEI

Page 4 of 14

Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
152-30 885.3050 885.4150	Bonnette, K.L. and P.D. Pyla (2001). An Acute Oral Toxicity Study in Mice with <i>E. coli</i> -Produced Cry3Bb1.11098(Q349R) Protein, Amended Final Report. MSL-17382. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455382-02	Monsanto Company	OWN	Dated November 5, 2001
152-30 885.3050	Leach, J.N., R.E. Hileman and J.D. Astwood (2001). Assessment of the <i>in vitro</i> Digestibility of Cry3Bb1 Protein Purified from Corn Event MON 863 and Cry3Bb1 Protein Purified from <i>E. coli</i> . MSL-17292. A pathogenicity determination is not applicable since <i>Cry3Bb1</i> is not a living organism.	455382-03	Monsanto Company	OWN	Dated November 5, 2001
152-30 885.3050	Hileman, R.E., J.N. Leach and J.D. Astwood (2001). Assessment of the <i>in vitro</i> Digestibility of Cry3bBb1.11098(Q349R) Protein in Simulated Intestinal Fluid. MSL-17530. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455770-02	Monsanto Company	OWN	Dated January 8, 2002
152-31 152-34 152-35 885.3100	Not applicable since Cry3Bb1 is a plant-incorporated active ingredient, is present at low levels, and there is little opportunity for dermal or ocular contact.				
152-32 885.3150	Not applicable since Cry3Bb1 is a plant-incorporated active ingredient, is present at low levels, and there is little opportunity for human inhalation exposure. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.				
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 20, 2003	

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DATA MATRIX

Date: February 20, 2003			EPA Reg. No./File Symbol: 524-LEI		Page 5 of 14
Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005			Product: Corn Event MON 863		
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
152-33 885.3200	Not applicable since Cry3Bb1 protein is neither infective nor pathogenic.				
151-36 885.2200	Hileman, R.E., E.A. Rice, R.E. Goodman and J.D. Aswood (2001). Bioinformatics Evaluation of the Cry3Bb1 Protein Produced in Corn Event MON 863 Utilizing Allergen, Toxin and Public Domain Protein Databases. MSL-17140.	454240-08	Monsanto Company	OWN	Dated May 21, 2001
152-36 152-37 152-38 885.3400	There is no clear published evidence that has demonstrated clinical allergic reactions to <i>Bt</i> crystal proteins. Monitoring for hypersensitivity incidents can be implemented after registration is granted.				
152-39 885.3500	Not applicable since Cry3Bb1 is not a living organism.				
154-16 885.4050	Gallagher, S.P., J. Grimes and J.B. Beavers (1999). <i>Bacillus thuringiensis</i> Protein 11231 in Corn Grain: A Dietary Toxicity Study with the Northern Bobwhite. MSL-16161. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-15	Monsanto Company	OWN	Dated August 19, 1999
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.		Date February 20, 2003

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DATA MATRIX

Date: February 20, 2003

EPA Reg. No./File Symbol: 524-LEI

Page 6 of 14

Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-17 885.4100	A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.				
154-18 885.4150	Not applicable since there is no reason to suspect that wild mammals would be any more sensitive to Cry3Bb1 than laboratory mammals. Mammals do not possess Cry protein receptors. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.				
154-19 885.4200	Li, M.H. and E.H. Robinson (1999). Evaluation of Insect Protected Corn Lines MON 853 and MON 859 as a Feed Ingredient for Catfish. MSL-16164. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-19	Monsanto Company	OWN	Dated August 19, 1999
154.19 885.2600	McKee, M.J. (2001) Bluegill Dietary Toxicity Study for the <i>Bacillus thuringiensis</i> Cry3Bb1 Protein Variant: A Waiver Request. MSL-17383.	455382-00	Monsanto Company	OWN	Dated November 5, 2001
154-20 885.4240	Drotar, K.R. and H.O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein I1098 in Corn Pollen: 48-Hour Static Renewal Acute Toxicity Test with the Cladoceran (<i>Daphnia magna</i>). MSL-15988. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-18	Monsanto Company	OWN	Dated August 19, 1999
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 20, 2003	

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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-21 885.4280	Results of acute toxicity tests with <i>Daphnia</i> and catfish did not produce any evidence of adverse effects. Testing with estuarine and marine species is not warranted because of very low to no potential for exposure to the Cry3 protein from field corn. A pathogenicity determination is not applicable since cry3Bb1 is not a living organism.				
154-22 885.4300	Cry3Bb1 is an insect toxin and Cry proteins have never been shown to cause toxicity in aquatic and terrestrial plants. The risk of outcrossing to weedy wild relatives is virtually nonexistent.				
154-23 885.4340	Palmer, S.J. and H.O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11231: Dietary Toxicity Study with the Ladybird Beetle (<i>Hippodamia convergens</i>). MSL-16166. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-14	Monsanto Company	OWN	Dated August 19, 1999
154-23 885.4340	Hoxter, K.A., S.J. Palmer and H.O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11231: An Acute Toxicity Study with Earthworm in an Artificial Soil Substrate. MSL-16162. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-16	Monsanto Company	OWN	Dated August 19, 1999
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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient: *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-23 885.4340	Teixeira, D. (1999). Assessment of Chronic Toxicity of Corn Tissue Containing the <i>Bacillus thuringiensis</i> Protein 11098 to Collembola (<i>Folsomia candida</i>). MSL-15988. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-17	Monsanto Company	OWN	Dated August 19, 1999
154-23 885.4340	Palmer, S.J. and H.O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11231: A Dietary Study with Green Lacewing Larvae (<i>Chrysoperla carnea</i>). MSL-16165. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-12	Monsanto Company	OWN	Dated August 19, 1999
154-23 885.4340	Palmer, S.J. and H.O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11231: A Dietary Study with the Parasitic Hymenoptera (<i>Nasonia vitripennis</i>). MSL-16166. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-13	Monsanto Company	OWN	Dated August 19, 1999
154-23 885.4340	Head, G. (2001). Research on the Effects of Corn Rootworm Protected Transgenic Corn Events on Nontarget Organisms: Preliminary Report. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	453484-02	Monsanto Company	OWN	Dated February 20, 2001
154-23 885.4340	Duan, J.J., G. Head, M. McKee and T.E. Nickson (2001). Dietary Effects of Transgenic <i>Bacillus thuringiensis</i> (Bt) Corn Pollen Expressing a Variant of Cry3Bb1 Protein on Adults of the Ladybird Beetle, <i>Coleomegilla maculata</i> . MSL-16936. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	453613-01	Monsanto Company	OWN	Dated March 20, 2001
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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-23 885.4340	Bryan, R.L., J.R. Porch and H.O. Krueger (2001). Dietary Effects of Transgenic BT Corn Pollen Expressing a Variant of Cry3Bb1 Protein on the Ladybird Beetle, <i>Hippodamia convergens</i> . MSL-17171. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	4553613-02	Monsanto Company	OWN	Dated March 20, 2001
154-23 885.4340	Bhatti, M.A., C.L. Pilcher, M.J. McKee, T.E. Nickson, G.P. Head and C.D. Pilcher (2001). Field Evaluation for the Ecological Impact of Corn Rootworm Insect-Protected Corn on Non-Target Organisms. MSL-17179. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455382-06	Monsanto Company	OWN	Dated November 5, 2001
154-23 885.4340	Duan, J.J., M.J. McKee and T.E. Nickson (2001). Dietary Effects of Transgenic <i>Bacillus thuringiensis</i> (Bt) Corn Pollen Expressing a Variant of Cry3Bb1 Protein on Larvae of the Ladybird Beetle, <i>Coleomegilla maculata</i> . MSL-16907. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455382-04	Monsanto Company	OWN	Dated November 5, 2001
154-23 885.4340	Sears, M. and M. Matilla (2002). Determination of the Toxicity of Corn Pollen Expressing a Cry3Bb1 Variant Protein to First Instar Monarch Butterfly Larvae (<i>Danix plexippus</i>) via Laboratory Bioassay. MSL-17235. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455382-05	Monsanto Company	OWN	Dated November 5, 2001
154-23 885.4340	Head, G., M. Pleau, S. Sivasubramanian and T. Vaughn (2001). Insecticidal Spectrum of Activity for Cry3Bb1 Protein <i>in vitro</i> . C3NTO. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455382-07	Monsanto Company	OWN	Dated November 5, 2001
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Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005		Product: Corn Event MON 863			
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-23 885.4340	Duan, J.J., M. J. McKee, G. Head and C.R. Brown (2002). Endangered Species Impact Assessment for Cry3Bb1 Protein in Transgenic Corn Event MON 863. MSL-17614. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455770-03	Monsanto Company	OWN	Dated January 8, 2002
154-23 885.4340	Head, G. (2002). Research on the Effects of Corn Rootworm Protected Transgenic Corn Events on Nontarget Organisms: Preliminary Results. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	456530-03	Monsanto Company	OWN	Dated April 9, 2002
154-23 885.4340	Bhatti, M. A., J. D. Duan, C. L. Pilcher, C. D. Pilcher, M. J. McKee, T. E. Nickson, G. P. Head and C. Jiang (2002). Ecological Assessment of Nontarget Organisms in the Plots of Corn Rootworm Insect Protected Corn Hybrid Containing MON 863 Event: 2000 - 2001 Field Trials. Report MSL-17521. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.		Monsanto Company	OWN	Dated September 10, 2002
154-23 885.4340	Sindermann, A. B., J. R. Porch and H. O. Krueger (2002). Evaluation of a Cry3Bb1 Protein Variant in an Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate. MSL-18137. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.		Monsanto Company	OWN	Dated September 10, 2002
154-24 885.4380	Maggi, V.L. (1999). Evaluation of the Dietary Effects of Purified <i>Bacillus thuringiensis</i> Protein 11231 on Honey Bee Larvae. MSL-16168. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-10	Monsanto Company	OWN	Dated August 19, 1999
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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-24 885.4380	Maggi, V.L. (1999). Evaluation of the Dietary Effect(s) of Purified <i>Bacillus thuringiensis</i> Protein 11231 on Adult Honey Bees (<i>Apis mellifera</i> L.). MSL-16169. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-11	Monsanto Company	OWN	Dated August 19, 1999
885.5200	Martin, J.W., M.J. McKee, S. Dubelman and Y.A. Dudin (2000). Aerobic Soil Degradation of the <i>B.t.</i> Protein 11098 as a Component of Insect Protected Corn. MSL-16440; an unpublished study conducted by Monsanto Company.	451568-04	Monsanto Company	OWN	Dated June 20, 2000
885.5200	Dubelman, S., B. Ayden, M. Mueth, J. A. Warren, C. Jiang, J. Bookout and Y. Dudin (2002). Aerobic Soil Degradation of the <i>Bacillus thuringiensis</i> Cry3Bb1 Variant Protein Produced in Corn Rootworm Protected Corn Event MON 863. MSL-17102.		Monsanto Company	OWN	Dated September 10, 2002
	Miller, D. (2000). Public Interest Document Supporting the Registration and Exemption from the Requirement of a Tolerance for the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry3Bb Protein, and the Genetic Material Necessary for its Production in Corn (Vectors ZMIR13L, ZMIR13L and ZMIR14L).	450297-01	Monsanto Company	OWN	Dated January 13, 2000
	Vaughn, T. (2001). Preliminary Results of Research on Insect Resistance Management for a Transgenic Corn Rootworm Control Product.	453484-01	Monsanto Company	OWN	Dated February 20, 2001
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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Pilcher, C.D., J.K. McFerson and D.P. Ward (2001). Agronomic Equivalency of Corn Event MON 863 Hybrids as Determined in Year 2000 Field Trials.	453484-03	Monsanto Company	OWN	Dated February 20, 2001
	Pilcher, C.D. (2001). Efficacy of MON 863 Against Corn Rootworm and Comparison to Insecticide Treatments - Results of Year 2000 Field Trials.	453613-03	Monsanto Company	OWN	Dated March 20, 2001
	Administrative Materials in Support of the Application for Registration of Event MON 863: Corn Rootworm Protected Corn (Vector ZMIR13L); EPA File Symbol 524-LEI	454240-00	Monsanto Company	OWN	Dated May 21, 2001
	Administrative Materials in Support of the Application for Registration of Event MON 863: Corn Rootworm Protected Corn (Vector ZMIR13L); EPA File Symbol 524-LEI	455382-00	Monsanto Company	OWN	Dated November 5, 2001
	Vaughn, T.T., M. Pleau, R. Knutson and T. Coombe (2001). Comparing the Efficacy of MON 863 and MON 863 to Three Corn Rootworm Species, Northern Corn Rootworm (<i>Diabrotica barberi</i>), Southern Corn Rootworm (<i>D. undecimpunctata howardi</i>), and Western Corn Rootworm (<i>D. lineolata</i>).	455382-08	Monsanto Company	OWN	Dated November 5, 2001
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Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Vaughn, T., D. Ward, J. Pershing, G. Head and J. McPerson (2001). An Interim Insect Resistance Management Plan for Corn Event MON 863: A Transgenic Corn Rootworm Control Product. MSL-17556.	455770-01	Monsanto Company	OWN	Dated January 8, 2002
	Ward, D. P. (2002). Public Interest Assessment Supporting Registration of <i>Bacillus thuringiensis</i> Cry3Bb1 Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in Corn Event MON 863. MSL-17766.	456530-01	Monsanto Company	OWN	Dated April 9, 2002
	Mitchell, P. D. (2002). Yield Benefit of Corn Event MON 863. MSL-17782.	456530-02	Monsanto Company	OWN	Dated April 9, 2002
	Alston, J. M., J. Hyde and M. C. Marra (2002). An Ex Ante Analysis of the Benefits from the Adoption of Monsanto's Corn Rootworm Resistant Varietal Technology - Yield Rootworm. MSL-17993.	456923-01	Monsanto Company	OWN	Dated June 10, 2002
151.20	Stone, T. (1993). Administrative Materials in Support of the Exemption from the Requirement of a Tolerance for Neomycin Phosphotransferase II as a Plant Pesticide Formulation Inert Ingredient. 93-132E.	430547-00	Monsanto Company	OWN	Dated November 23, 1993
Signature			Name and Title Dennis P. Ward, Ph.D Regulatory Affairs Mgr.	Date February 20, 2003	

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Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
152-30	Naylor, M. W. (1992). Acute Oral Toxicity Study of Neomycin Phosphotransferase (NPTII) in Albino Mice. ML-91-409. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	430547-01	Monsanto Company	OWN	Dated November 23, 1993
152.30	Ream, J. E. (1993). Assessment of Degradation of Neomycin Phosphotransferase II in <i>In vitro</i> Mammalian Digestion Models. IRC-91-ANA-06. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	430933-02	Monsanto Company	OWN	Dated November 23, 1993
	Literature Cited in Submission Supporting the Exemption from the Requirement of a Tolerance for the Plant Pesticide Formulation Inert Ingredient Neomycin Phosphotransferase II.	430547-02	Monsanto Company	PL	Dated November 23, 1993
Signature			Name and Title Dennis P. Ward, Ph.D Regulatory Affairs Mgr.		Date February 20, 2003



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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient: *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated January 8, 2002
			Monsanto Company	OWN	Dated November 5, 2001
			Monsanto Company	OWN	Dated May 21, 2001
			Monsanto Company	OWN	Dated May 21, 2001
			Monsanto Company	OWN	Dated May 21, 2001
			Monsanto Company	OWN	Dated May 21, 2001
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Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005			Product: Corn Event MON 863		
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated June 20, 2000
			Monsanto Company	OWN	Dated June 24, 1997
			Monsanto Company	OWN	Dated August 19, 1999
			Monsanto Company	OWN	Dated May 21, 2001
			Monsanto Company	OWN	Dated May 21, 2001
Signature		Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.		Date February 20, 2002	

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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated November 5, 2001
			Monsanto Company	OWN	Dated April 7, 2001
			Monsanto Company	OWN	Dated May 21, 2001
			Monsanto Company	OWN	May 21, 2001
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 20, 2003	

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DATA MATRIX

Date: February 20, 2003

EPA Reg. No./File Symbol: 524-[]-[]


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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated November 5, 2001
			Monsanto Company	OWN	Dated November 5, 2001
			Monsanto Company	OWN	Dated January 8, 2002
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 20, 2003	

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DATA MATRIX

Date: February 20, 2003

EPA Reg. No./File Symbol: 524-LEI

Page 5 of 14

Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated May 21, 2001
			Monsanto Company	OWN	Dated August 19, 1999
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 20, 2003	

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DATA MATRIX

Date: February 20, 2003

EPA Reg. No./File Symbol: 524-LEI

Page 6 of 14

Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated August 19, 1999
			Monsanto Company	OWN	Dated November 5, 2001
			Monsanto Company	CW1	Dated August 19, 2001
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.		Date February 20, 2003

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DATA MATRIX

Date: February 20, 2003			EPA Reg. No./File Symbol: 524-LEI		Page 7 of 14
Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005			Product: Corn Event MON 863		
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					
			Monsanto Company	OWN	Dated August 19, 1999
			Monsanto Company	CV/11	Dated August 19, 1999
Signature		Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.		Date February 20, 2003	

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DATA MATRIX

Date: February 20, 2003			EPA Reg. No./File Symbol: 524-1-1E1		Page 8 of 14
Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005			Product: Corn Event MON 863		
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated August 19, 1999
			Monsanto Company	OWN	Dated August 19, 1999
			Monsanto Company	OWN	Dated August 19, 1999
			Monsanto Company	OWN	Dated February 20, 2001
			Monsanto Company	OWN	Dated March 20, 2001
			Monsanto Company	OWN	
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 20, 2003	

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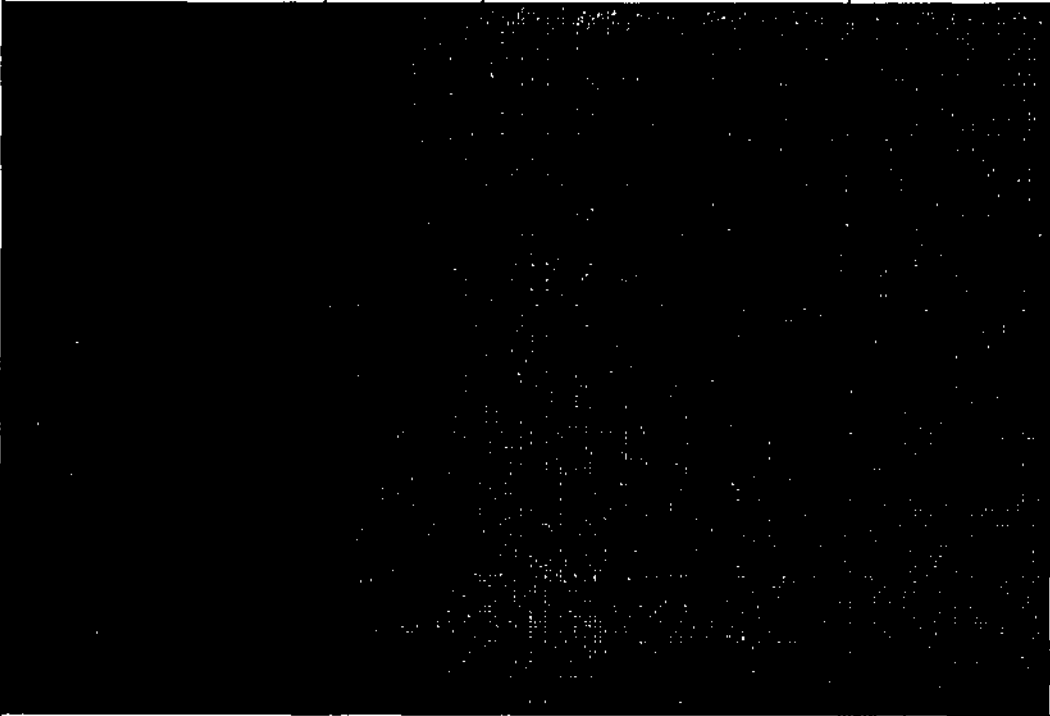


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Date: February 20, 2003		EPA Reg. No./File Symbol: 524-L[E]		Page 9 of 14	
Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005		Product: Corn Event MON 863			
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated March 20, 2001
			Monsanto Company	OWN	Dated November 5, 2001
			Monsanto Company	OWN	Dated November 5, 2001
			Monsanto Company	OWN	Dated November 5, 2001
			Monsanto Company	OWN	Dated November 5, 2001
Signature		Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.		Date: February 20, 2003	

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DATA MATRIX

Date: February 20, 2003

EPA Reg. No./File Symbol: 524-1.1E1

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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated January 8, 2002
			Monsanto Company	OWN	Dated April 9, 2002
			Monsanto Company	OWN	Dated September 10, 2002
			Monsanto Company	OWN	Dated September 10, 2002
			Monsanto Company	OWN	Dated August 19, 1999
			Signature		Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.

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DATA MATRIX

Date: February 20, 2003		EPA Reg. No./File Symbol: 524-LJEI		Page 11 of 14	
Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005		Product: Corn Event MON 863			
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated August 19, 1999
			Monsanto Company	OWN	Dated June 20, 2000
			Monsanto Company	OWN	Dated September 10, 2002
			Monsanto Company	OWN	Dated January 13, 2000
			Monsanto Company	OWN	Dated February 20, 2001
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 20, 2003	

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DATA MATRIX

Date: February 20, 2003

EPA Reg. No./File Symbol: 524-LEI

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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated February 20, 2001
			Monsanto Company	OWN	Dated March 20, 2001
			Monsanto Company	OWN	Dated May 21, 2001
			Monsanto Company	OWN	Dated November 5, 2001
			Monsanto Company	OWN	Dated November 5, 2001
			Monsanto Company	CW/1	Dated February 20, 2003
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.		

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DATA MATRIX

Date: February 20, 2003		EPA Reg. No./File Symbol: 524-LEI		Page 13 of 14	
Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005		Product: Corn Event MON 863			
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated January 8, 2002
			Monsanto Company	OWN	Dated April 9, 2002
			Monsanto Company	OWN	Dated April 9, 2002
			Monsanto Company	OWN	Dated June 10, 2002
			Monsanto Company	CVR	Dated November 23, 1993
Signature		Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.		Date February 20, 2003	

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DATA MATRIX

Date: February 20, 2003

EPA Reg. No./File Symbol: 524-L-111

Page 14 of 14

Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient: *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated November 23, 1993
			Monsanto Company	OWN	Dated November 23, 1992
			Monsanto Company	PL	Dated November 23, 1993
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 20, 2003	

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CONFIDENTIAL STATEMENT OF FORMULA

{ CBI Cross Reference Number 1 }

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CONFIDENTIAL STATEMENT OF FORMULA

{CBI Cross Reference Number 1}

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PRODUCT LABEL

Five copies of the proposed label for 'Corn Event MON 863: Rootworm Protected Corn' are attached. This label supersedes the label previously submitted to EPA, dated February 11, 2003.

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Corn Event MON 863: Rootworm Protected Corn

[Alternate brand name: *YieldGard® Rootworm: Rootworm Protection*]

This product is effective in controlling damage caused by corn rootworm larval feeding on corn roots.

Active Ingredient:

Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary for its production (ZMIR13L) in event MON 863 corn.....0.001 - 0.006%

Other Ingredients:

Substance produced by a marker gene and the genetic material necessary for its production (ZMIR13L) in event MON 863 corn.....0.00002 – 0.00003%

Percentage (wt/wt) on a dry weight basis.

Keep Out of Reach of Children

CAUTION

® YieldGard is a trademark of Monsanto Technology LLC

EPA Registration No. 524-528

EPA Establishment No. 524-MO-002

©2003 Monsanto Company
700 Chesterfield Parkway West
St. Louis, MO 63017

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling.

The following information regarding commercial production must be included in the Event MON 863 Technology Use Guide.

Insect Resistance Management

Growers of Corn Event MON 863: Rootworm Protected Corn must adhere to the following refuge requirements. Growers must plant a structured refuge of at least 20% non-event MON 863 corn.

Refuge planting options include: adjacent blocks or in-field strips. If blocks are implemented they must be adjacent to the Corn Event MON 863 field. If in-field strips within a corn field are implemented, then at least 6, and preferably 12 consecutive rows should be planted with non-event MON 863 corn.

The refuge and Corn Event MON 863 acres should be managed under comparable agronomic regimes. Refuge and Corn Event MON 863 acres should both be irrigated if irrigation is used. In regions where corn is cropped continuously, refuge and Corn Event MON 863 acres should be planted in a continuous cropping regime. The refuge may be placed only on first-year corn acres if the Event MON 863 corn is planted on first-year corn acres.

Growers have the option of applying conventional insecticides to the corn refuge for control of corn rootworm larvae. Growers are not permitted to apply agents for control of adult corn rootworm to the refuge as this would render the refuge less effective. If growers opt to treat for other insects present in the refuge while adult corn rootworm are present, then the Corn Event MON 863 acres must be treated in a like manner.

These refuge requirements do not apply to operations engaged in the propagation of inbred seed corn.

Corn Insects Controlled or Suppressed

Corn has been genetically transformed to produce the *B.t.* protein, Cry3Bb1, for control or suppression of the following coleopteran insects:

Western corn rootworm (*Diabrotica virgifera virgifera*)

Northern corn rootworm (*Diabrotica barberi*)

Mexican corn rootworm (*Diabrotica virgifera zea*)

CONFIDENTIAL ATTACHMENT

MONSANTO



Amendment of the Application to Register a *Bacillus thuringiensis*
Cry3Bb1 Protein and the Genetic Material Necessary for its
Production (Vector ZMIR13L) in Event MON 863 Corn;
EPA File Symbol 524-LEI

CONFIDENTIAL ATTACHMENT

AUTHOR

Dennis P. Ward, Ph.D.
Regulatory Affairs Manager

DATE

February 20, 2003

SUBMITTING REGISTRANT

Monsanto Company
600 13th Street N.W.
Suite 660
Washington, DC 20005

MONSANTO REFERENCE No.

00-CR-032E-17

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CONFIDENTIAL BUSINESS INFORMATION

CBI Cross Reference Number 1

This cross reference number noted on a place holder page is used in place of the following whole page at the indicated volume and page references

The deleted Page is attached immediately behind this page.

<u>Pages</u>	<u>Reason for Deletion</u>	<u>FIFRA Reference</u>
37 & 38	Discloses commercial information	§10(d)(1)(A), (B) or (C)

MONSANTO



Dennis P. Ward, Ph.D.
Regulatory Affairs Manager
(636) 737-6631

MONSANTO COMPANY
600 13TH STREET, N.W.
SUITE 660
WASHINGTON, D.C. 20005
PHONE (202) 783-2460
FAX (202) 783-2468
<http://www.monsanto.com>

February 20, 2003

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U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

RECEIVED
FEB 26 2003
OPP/BPPD

Attn: Phillip O. Hutton, Team Leader 90

Subj: Amendment to application for registration of Corn Event MON 863
EPA File Symbol 524-LEI

Dear Mr. Hutton:

In support of our application to register Corn Event MON 863 we are submitting a revised data matrix, label and Confidential Statement of Formula. Contained within the Data Matrix are numerous requests for data waivers. These waiver requests are based primarily on the low potential for exposure to Cry3Bb1 protein and the fact that many of microbial pesticide data requirements (49 CFR 158.740) are not applicable to a plant-incorporated protectant.

Enclosed with this submission are the following materials:

- Application for Pesticide (EPA Form 8570-1)
- Certification with Respect to Citation of Data (EPA Form 8570-34)
- Data Matrix (EPA Form 8570-35)
- Product label (5 copies)
- Confidential attachment

Except for the materials contained in the confidential attachment, Monsanto does not object to placement of materials contained in this submission in the Public Docket.

Should you require any additional information regarding this submission please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (636-737-6631).



Sincerely,

Dennis P. Ward, Ph.D.

Mr. P. Hutton
2/20/2003
Page 2 of 45

Att: Administrative materials

cc: Mike Mendelsohn, EPA/OPP/BPPD
Russell Schneider, Monsanto

 <div style="display: inline-block; text-align: center;"> United States Environmental Protection Agency Washington, DC 20460 </div>		<input checked="" type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide – Section I			
1. Company/Product Number File Symbol 524-LEI		2. EPA Product Manager Phillip O. Hutton	
Company/Product (Name) Com Event MON 863		PM # 90	
5. Name and Address of Applicant (Include ZIP Code) Monsanto Company 600 13 th St., N.W., Suite 660 Washington, DC 20005 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
Section – II			
<input type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification – Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input checked="" type="checkbox"/> Other – Explain below.	
Explanation: Use additional page(s) if necessary. (For Section I and Section II.) Submission of request for data waivers and revised data matrix, labeling and CSF in support of application to register Com Event MON 863			
Section – III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No * Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per Container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package wgt. No. per Container	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	
5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product		6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	
Section – IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Russell P. Schneider		Title Regulatory Affairs Director	
Telephone No. (Include Area Code) (202) 383-2866		6. Date Application Received (Stamped)	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			
2. Signature 		3. Title Regulatory Affairs Manager	
4. Typed Name Dennis P. Ward Tel. (636) 737-6631		5. Date February 20, 2003	



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401 M Street, S. W.
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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number:

Monsanto Company, 600 13th Street, N.W., Washington, DC 2005 (202) 383-2866

EPA Registration Number / File Symbol:

524-LEI

Active Ingredient(s) and/or representative test compound(s): B.t. Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Date:

February 20, 2003

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158:

Terrestrial field crop

Product Name:

Corn Event MON 863

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).



I am responding to a Data-Call-in Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

Section I: METHOD OF DATA SUPPORT (Check one method only)



I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).



I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

Section II: GENERAL OFFER TO PAY



[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

Section III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under the applicable law.

Signature

Date

February 20, 2003

Typed or Printed Name and Title

Dennis P. Ward, Regulatory Affairs
Manager




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DATA MATRIX

Date: February 20, 2003		EPA Reg. No./File Symbol: 524-LEI		Page 1 of 14	
Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005		Product: Corn Event MON 863			
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151-20, 151-21, 151-25 885.1100 885.1200 885.1500	Administrative Materials for Amendment of Application to Registrant of a <i>Bacillus thuringiensis</i> Cry3Bb1 Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in Corn Event MON 863; EPA File Symbol LEI-524.	455770-00	Monsanto Company	OWN	Dated January 8, 2002
151-20, 153-4 885.1100 885.2200	Holleschak, G., R.E. Hileman and J.D. Astwood (2001). Immuno-detectability of NPTII Protein in the Grain of Insect Protected Corn Event MON 863 After Heat Treatment. MSL-17300.	455382-09	Monsanto Company	OWN	Dated November 5, 2001
151-20, 151-21, 151-22, 151-26 885.1100 885.1200 885.1300 885.2100	Cavato, T.A., E.C. Rigden, D.W. Mittanck and R.P. Lirette (2001). Amended Report for MSL-16505: Molecular Analysis of Corn Event MON 863. MSL-17152.	454240-02	Monsanto Company	OWN	Dated May 21, 2001
151-20, 153-4 885.1100 885.2200	Holleschak, G., R.E. Hileman and J.D. Astwood (2001). Amended Report for MSL-16597: Immunodetectability of Cry3Bb1.11098 and Cry3Bb1.11231 Proteins in the Grain of Insect Protected Corn Events MON 863 and MON 853 After Heat Treatment. MSL-17223.	454240-07	Monsanto Company	OWN	Dated May 21, 2001
151-23, 151-25, 153-4, 151-26, 885.1400, 885.1500 885.2200 885.2400 885.2500	Dudin, Y.A., B-P. Tonnu, L.D. Albee and R.P. Lirette (2001). Amended Report for MSL-16559: <i>B.t.</i> Cry3Bb1.11098 and NPTII Protein Levels in Sample Tissue Collected from Corn Event MON 863 Grown in 1999 Field Trials. MSL-171811.	454240-01	Monsanto Company	OWN	Dated May 21, 2001
Signature 			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.		Date February 20, 2003

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EPA Reg. No./File Symbol: 524-LEI

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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151-26 885.2100	Administrative Materials in Support of the Registration of <i>Bacillus thuringiensis</i> Cry3Bb Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in Corn; and Amendment of the Previous Request for Exemption from the Requirement of a Tolerance, PP7F4888	451568-00	Monsanto Company	OWN	Dated June 20, 2000
151-26 885.2100	Petition from the Requirement of a Tolerance for <i>Bacillus thuringiensis</i> Cry1, Cry2, and Cry3 Classes of Proteins and the Genetic Material Necessary for the Production of These Proteins In or On All Raw Agricultural Commodities When used as Plant-Pesticide Active Ingredient	PP 7F4888	Monsanto Company	OWN	Dated June 24, 1997
151-26 885.2100	Pilacinski, W. P. and M. W. Taylor (1999). Administrative Materials in Support of the Registration of the Plant-Expressed Protectant <i>Bacillus thuringiensis</i> Corn Rootworm Control Protein, as Produced in the Corn (<i>Zea mays</i> , L.), and the Amendment to the Previous Request for Exemption from the Requirement of a	449043-00	Monsanto Company	OWN	Dated August 19, 1999
151-26 885.2100	Hileman, R.E. and J.D. Astwood (2001). Additional Characterization of the Cry3Bb1 Protein Produced in Corn Event MON 863. MSL-17137.	454240-10	Monsanto Company	OWN	Dated May 21, 2001
151-26 885.2100	Thoma, R.S., G. Holleschak, R.E. Hileman and J.D. Astwood (2001). Primary Structural Protein Characterization of Corn Event MON 863 Cry3Bb1.11098 Protein Using N-terminal Sequencing and MALDI Time of Flight Mass Spectrometric Techniques. MSL-17154.	454240-11	Monsanto Company	OWN	Dated May 21, 2001
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 20, 2003	

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Date: February 20, 2003		EPA Reg. No./File Symbol: 524-LEI		Page 3 of 14	
Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005		Product: Corn Event MON 863			
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151-26 885.2100	Hileman, R.E., G. Holleschak, L.A. Turner, R.S. Thomas, C.R. Brown and J.D. Astwood (2001). Characterization and Equivalence of the Cry3Bb1 Protein Produced by <i>E. coli</i> Fermentation and Corn Event MON 863. MSL-17274.	455382-01	Monsanto Company	OWN	Dated November 5, 2001
151-25 885.2300	D. Kolwyck, B-P. Tonnu, Y. A. Dudin, T. Ploesser and K. Gustafson (2001). Validated Method for Extraction and Direct ELISA Analysis of Cry3Bb1 in Corn Grain.	453731-01	Monsanto Company	OWN	Dated April 7, 2001
151-27 885.2400	Samples will be submitted as part of the independent laboratory method validation work that is ongoing.				
153-4 885.2500	Dudin, Y.A., B-P. Tonnu, L.D. Albee and R.P. Lirette (2001). Amended Report for MSL-16559: <i>B.t.</i> Cry3Bb1.11098 and NPTII Protein Levels in Sample Tissue Collected from Corn Event MON 863 Grown in 1999 Field Trials. MSL-17181L.	454240-01	Monsanto Company	OWN	Dated May 21, 2001
152-30 885.3050	Astwood, J.D., R.E. Hileman, M.J. McKee, T.J. Rydel, J.W. Seale and L. English (2001). Safety Assessment of Cry3Bb1 Variants in Corn Rootworm Protected Corn. MSL-17225. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	454240-09	Monsanto Company	OWN	Dated May 21, 2001
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Date: February 20, 2003		EPA Reg. No./File Symbol: 524-LEI		Page 4 of 14	
Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005		Product: Corn Event MON 863			
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZM1R13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
152-30 885.3050 885.4150	Bonnette, K.L. and P.D. Pyla (2001). An Acute Oral Toxicity Study in Mice with <i>E. coli</i> Produced Cry3Bb1.11098(Q349R) Protein, Amended Final Report. MSL-17382. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455382-02	Monsanto Company	OWN	Dated November 5, 2001
152-30 885.3050	Leach, J.N., R.E. Hileman and J.D. Astwood (2001). Assessment of the <i>in vitro</i> Digestibility of Cry3Bb1 Protein Purified from Corn Event MON 863 and Cry3Bb1 Protein Purified from <i>E. coli</i> . MSL-17292. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455382-03	Monsanto Company	OWN	Dated November 5, 2001
152-30 885.3050	Hileman, R.E., J.N. Leach and J.D. Astwood (2001). Assessment of the <i>in vitro</i> Digestibility of Cry3bBb1.11098(Q349R) Protein in Simulated Intestinal Fluid. MSL-17530. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455770-02	Monsanto Company	OWN	Dated January 8, 2002
152-31 152-34 152-35 885.3100	Not applicable since Cry3Bb1 is a plant-incorporated active ingredient, is present at low levels, and there is little opportunity for dermal or ocular contact.				
152-32 885.3150	Not applicable since Cry3Bb1 is a plant-incorporated active ingredient, is present at low levels, and there is little opportunity for human inhalation exposure. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.				
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.		Date February 20, 2003

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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
152-33 885.3200	Not applicable since Cry3Bb1 protein is neither infective nor pathogenic.				
151-36 885.2200	Hileman, R.E., E.A. Rice, R.E. Goodman and J.D. Astwood (2001). Bioinformatics Evaluation of the Cry3Bb1 Protein Produced in Corn Event MON 863 Utilizing Allergen, Toxin and Public Domain Protein Databases. MSL-17140.	454240-08	Monsanto Company	OWN	Dated May 21, 2001
152-36 152-37 152-38 885.3400	There is no clear published evidence that has demonstrated clinical allergic reactions to <i>Bt</i> crystal proteins. Monitoring for hypersensitivity incidents can be implemented after registration is granted.				
152-39 885.3500	Not applicable since Cry3Bb1 is not a living organism.				
154-16 885.4050	Gallagher, S.P., J. Grimes and J.B. Beavers (1999). <i>Bacillus thuringiensis</i> Protein 11231 in Corn Grain: A Dietary Toxicity Study with the Northern Bobwhite. MSL-16161. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-15	Monsanto Company	OWN	Dated August 19, 1999
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 20, 2003	

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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-17 885.4100	A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.				
154-18 885.4150	Not applicable since there is no reason to suspect that wild mammals would be any more sensitive to Cry3Bb1 than laboratory mammals. Mammals do not possess Cry protein receptors. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.				
154-19 885.4200	Li, M.H. and E.H. Robinson (1999). Evaluation of Insect Protected Corn Lines MON 853 and MON 859 as a Feed Ingredient for Catfish. MSL-16164. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-19	Monsanto Company	OWN	Dated August 19, 1999
154-19 885.2600	McKee, M.J. (2001) Bluegill Dietary Toxicity Study for the <i>Bacillus thuringiensis</i> Cry3Bb1 Protein Variant: A Waiver Request. MSL-17383.	455382-00	Monsanto Company	OWN	Dated November 5, 2001
154-20 885.4240	Drott, K.R. and H.O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11098 in Corn Pollen: 48-Hour Static Renewal Acute Toxicity Test with the Cladoceran (<i>Daphnia magna</i>). MSL-15988. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-18	Monsanto Company	OWN	Dated August 19, 1999
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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-21 885.4280	Results of acute toxicity tests with <i>Daphnia</i> and catfish did not produce any evidence of adverse effects. Testing with estuarine and marine species is not warranted because of very low to no potential for exposure to the Cry3 protein from field corn. A pathogenicity determination is not applicable since cry3Bb1 is not a living organism.				
154-22 885.4300	Cry3Bb1 is an insect toxin and Cry proteins have never been shown to cause toxicity in aquatic and terrestrial plants. The risk of outcrossing to weedy wild relatives is virtually nonexistent.				
154-23 885.4340	Palmer, S.J. and H.O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11231: Dietary Toxicity Study with the Ladybird Beetle (<i>Hippodamia convergens</i>). MSL-16166. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-14	Monsanto Company	OWN	Dated August 19, 1999
154-23 885.4340	Hoxter, K.A., S.J. Palmer and H.O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11231: An Acute Toxicity Study with Earthworm in an Artificial Soil Substrate. MSL-16162. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-16	Monsanto Company	OWN	Dated August 19, 1999
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 20, 2003	

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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-23 885.4340	Teixeira, D. (1999). Assessment of Chronic Toxicity of Corn Tissue Containing the <i>Bacillus thuringiensis</i> Protein 11098 to Collembola (<i>Folsomia candida</i>). MSL-15988. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-17	Monsanto Company	OWN	Dated August 19, 1999
154-23 885.4340	Palmer, S.J. and H.O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11231: A Dietary Study with Green Lacewing Larvae (<i>Chrysoperla carnea</i>). MSL-16165. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-12	Monsanto Company	OWN	Dated August 19, 1999
154-23 885.4340	Palmer, S.J. and H.O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11231: A Dietary Study with the Parasitic Hymenoptera (<i>Nasonia vitripennis</i>). MSL-1616. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-13	Monsanto Company	OWN	Dated August 19, 1999
154-23 885.4340	Head, G. (2001). Research on the Effects of Corn Rootworm Protected Transgenic Corn Events on Nontarget Organisms: Preliminary Report. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	453484-02	Monsanto Company	OWN	Dated February 20, 2001
154-23 885.4340	Duan, J.J., G. Head, M. McKee and T.E. Nickson (2001). Dietary Effects of Transgenic <i>Bacillus thuringiensis</i> (Bt) Corn Pollen Expressing a Variant of Cry3Bb1 Protein on Adults of the Ladybird Beetle, <i>Coleomegilla maculata</i> . MSL-16936. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	453613-01	Monsanto Company	OWN	Dated March 20, 2001
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 20, 2003	

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Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005		Product: Corn Event MON 863			
Ingredient: <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-23 885.4340	Bryan, R.L., J.R. Porch and H.O. Krueger (2001). Dietary Effects of Transgenic BT Corn Pollen Expressing a Variant of Cry3Bb1 Protein on the Ladybird Beetle, <i>Hippodamia convergens</i> . MSL-17171. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	453613-02	Monsanto Company	OWN	Dated March 20, 2001
154-23 885.4340	Bhatti, M.A., C.L. Pilcher, M.J. McKee, T.E. Nickson, G.P. Head and C.D. Pilcher (2001). Field Evaluation for the Ecological Impact of Corn Rootworm Insect-Protected Corn on Non-Target Organisms. MSL-17179. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455382-06	Monsanto Company	OWN	Dated November 5, 2001
154-23 885.4340	Duan, J.J., M.J. McKee and T.E. Nickson (2001). Dietary Effects of Transgenic <i>Bacillus thuringiensis</i> (Bt) Corn Pollen Expressing a Variant of Cry3Bb1 Protein on Larvae of the Ladybird Beetle, <i>Coleomegilla maculata</i> . MSL-16907. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455382-04	Monsanto Company	OWN	Dated November 5, 2001
154-23 885.4340	Sears, M. and M. Mattila (2002). Determination of the Toxicity of Corn Pollen Expressing a Cry3Bb1 Variant Protein to First Instar Monarch Butterfly Larvae (<i>Danix plexippus</i>) via Laboratory Bioassay. MSL-17235. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455382-05	Monsanto Company	OWN	Dated November 5, 2001
154-23 885.4340	Head, G., M. Pleau, S. Sivasubramanian and T. Vaughn (2001). Insecticidal Spectrum of Activity for Cry3Bb1 Protein <i>in vitro</i> . C3NTO. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455382-07	Monsanto Company	OWN	Dated November 5, 2001
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 20, 2003	

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Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005		Product: Corn Event MON 863			
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-23 885.4340	Duan, J.J., M. J. McKee, G. Head and C.R. Brown (2002). Endangered Species Impact Assessment for Cry3Bb1 Protein in Transgenic Corn Event MON 863. MSL-17614. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455770-03	Monsanto Company	OWN	Dated January 8, 2002
154-23 885.4340	Head, G. (2002). Research on the Effects of Corn Rootworm Protected Transgenic Corn Events on Nontarget Organisms: Preliminary Results. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	456530-03	Monsanto Company	OWN	Dated April 9, 2002
154-23 885.4340	Bhatti, M. A., J. D. Duan, C. L. Pilcher, C. D. Pilcher, M. J. McKee, T. E. Nickson, G. P. Head and C. Jiang (2002). Ecological Assessment of Nontarget Organisms in the Plots of Corn Rootworm Insect Protected Corn Hybrid Containing MON 863 Event: 2000 - 2001 Field Trials. Report MSL-17521. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.		Monsanto Company	OWN	Dated September 10, 2002
154-23 885.4340	Sindermann, A. B., J. R. Porsch and H. O. Krueger (2002). Evaluation of a Cry3Bb1 Protein Variant in an Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate. MSL-18137. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.		Monsanto Company	OWN	Dated September 10, 2002
154-24 885.4380	Maggi, V.L. (1999). Evaluation of the Dietary Effects of Purified <i>Bacillus thuringiensis</i> Protein 11231 on Honey Bee Larvae. MSL-16168. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-10	Monsanto Company	OWN	Dated August 19, 1999
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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-24 885.4380	Maggi, V.L. (1999). Evaluation of the Dietary Effect(s) of Purified <i>Bacillus thuringiensis</i> Protein 11231 on Adult Honey Bees (<i>Apis mellifera</i> L.). MSL-16169. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-11	Monsanto Company	OWN	Dated August 19, 1999
885.5200	Martin, J.W., M.J. McKee, S. Dubelman and Y.A. Dudin (2000). Aerobic Soil Degradation of the <i>B.t.</i> Protein 11098 as a Component of Insect Protected Corn. MSL-16440; an unpublished study conducted by Monsanto Company.	451568-04	Monsanto Company	OWN	Dated June 20, 2000
885.5200	Dubelman, S., B. Ayden, M. Mueth, J. A. Warren, C. Jiang, J. Bookout and Y. Dudin (2002). Aerobic Soil Degradation of the <i>Bacillus thuringiensis</i> Cry3Bb1 Variant Protein Produced in Corn Rootworm Protected Corn Event MON 863. MSL-17102.		Monsanto Company	OWN	Dated September 10, 2002
	Miller, D. (2000). Public Interest Document Supporting the Registration and Exemption from the Requirement of a Tolerance for the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry3Bb Protein, and the Genetic Material Necessary for its Production in Corn (Vectors ZMIR13L, ZMIR13L, and ZMIR13L).	450297-01	Monsanto Company	OWN	Dated January 13, 2000
	Vaughn, T. (2001). Preliminary Results of Research on Insect Resistance Management for a Transgenic Corn Rootworm Control Product.	453484-01	Monsanto Company	OWN	Dated February 20, 2001
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Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Pilcher, C.D., J.K. McFerson and D.P. Ward (2001). Agronomic Equivalency of Corn Event MON 863 Hybrids as Determined in Year 2000 Field Trials.	453484-03	Monsanto Company	OWN	Dated February 20, 2001
	Pilcher, C.D. (2001). Efficacy of MON 863 Against Corn Rootworm and Comparison to Insecticide Treatments - Results of Year 2000 Field Trials.	453613-03	Monsanto Company	OWN	Dated March 20, 2001
	Administrative Materials in Support of the Application for Registration of Event MON 863: Corn Rootworm Protected Corn (Vector ZMIR13L); EPA File Symbol 524-LEI	454240-00	Monsanto Company	OWN	Dated May 21, 2001
	Administrative Materials in Support of the Application for Registration of Event MON 863: Corn Rootworm Protected Corn (Vector ZMIR13L); EPA File Symbol 524-LEI	455382-00	Monsanto Company	OWN	Dated November 5, 2001
	Vaughn, T.T., M. Pleau, R. Knutson and T. Coombe (2001). Comparing the Efficacy of MON 863 and MON 863 to Three Corn Rootworm Species, Northern Corn Rootworm (<i>Diabrotica barberi</i>), Southern Corn Rootworm (<i>D. undecimpunctata howardi</i>), and Western Corn Rootworm (<i>D. virgifera virgifera</i>). MTC 01-001	455382-08	Monsanto Company	OWN	Dated November 5, 2001
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Ingredient: <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Vaughn, T., D. Ward, J. Pershing, G. Head and J. McPerson (2001). An Interim Insect Resistance Management Plan for Corn Event MON 863: A Transgenic Corn Rootworm Control Product. MSL-17556.	455770-01	Monsanto Company	OWN	Dated January 8, 2002
	Ward, D. P. (2002). Public Interest Assessment Supporting Registration of <i>Bacillus thuringiensis</i> Cry3Bb1 Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in Corn Event MON 863. MSL-17766.	456530-01	Monsanto Company	OWN	Dated April 9, 2002
	Mitchell, P. D. (2002). Yield Benefit of Corn Event MON 863. MSL-17782.	456530-02	Monsanto Company	OWN	Dated April 9, 2002
	Alston, J. M., J. Hyde and M. C. Marra (2002). An Ex Ante Analysis of the Benefits from the Adoption of Monsanto's Corn Rootworm Resistant Varietal Technology - Yield [®] Rootworm. MSL-17993.	456923-01	Monsanto Company	OWN	Dated June 10, 2002
151.20	Stone, T. (1993). Administrative Materials in Support of the Exemption from the Requirement of a Tolerance for Neomycin Phosphotransferase II as a Plant Pesticide Formulation Inert Ingredient. 93-132E	430547-00	Monsanto Company	OWN	Dated November 23, 1993
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Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
152-30	Naylor, M. W. (1992). Acute Oral Toxicity Study of Neomycin Phosphotransferase (NPTII) in Albino Mice. ML-91-409. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	430547-01	Monsanto Company	OWN	Dated November 23, 1993
152.30	Ream, J. E. (1993). Assessment of Degradation of Neomycin Phosphotransferase II in <i>In vitro</i> Mammalian Digestion Models. IRC-91-ANA-06. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	430933-02	Monsanto Company	OWN	Dated November 23, 1993
	Literature Cited in Submission Supporting the Exemption from the Requirement of a Tolerance for the Plant Pesticide Formulation Inert Ingredient Neomycin Phosphotransferase II.	430547-02	Monsanto Company	PL	Dated November 23, 1993
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Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated January 8, 2002
			Monsanto Company	OWN	Dated November 5, 2001
			Monsanto Company	OWN	Dated May 21, 2001
			Monsanto Company	OWN	Dated May 21, 2001
			Monsanto Company	OWN	Dated May 21, 2001
			Monsanto Company	OWN	Dated May 21, 2001

Signature

Name and Title

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Regulatory Affairs Mgr.

Date

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Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated June 20, 2000
			Monsanto Company	OWN	Dated June 24, 1997
			Monsanto Company	OWN	Dated August 19, 1999
			Monsanto Company "	OWN	Dated May 21, 2001
			Monsanto Company	OWN	Dated May 21, 2001
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Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated November 5, 2001
			Monsanto Company	OWN	Dated April 7, 2001
			Monsanto Company	OWN	Dated May 21, 2001
			Monsanto Company	OWN	May 21, 2001
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Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated November 5, 2001
			Monsanto Company	OWN	Dated November 5, 2001
			Monsanto Company	OWN	Dated January 8, 2002
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Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated May 21, 2001
			Monsanto Company	OWN	Dated August 19, 1999
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.		Date February 20, 2003

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Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated August 19, 1999
			Monsanto Company	OWN	Dated November 5, 2001
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Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					
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Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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			Monsanto Company	OWN	Dated August 19, 1999
			Monsanto Company	OWN	Dated August 19, 1999
			Monsanto Company	OWN	Dated February 20, 2001
			Monsanto Company	OWN	Dated March 20, 2001
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00-CR-032E-19

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Date: February 20, 2003

EPA Reg. No./File Symbol: 524-LEI

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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated March 20, 2001
			Monsanto Company	OWN	Dated November 5, 2001
			Monsanto Company	OWN	Dated November 5, 2001
			Monsanto Company	OWN	Dated November 5, 2001
			Monsanto Company	OWN	Dated November 5, 2001
			Monsanto Company	OWN	Dated November 5, 2001
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 20, 2003	

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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated January 8, 2002
			Monsanto Company	OWN	Dated April 9, 2002
			Monsanto Company	OWN	Dated September 10, 2002
			Monsanto Company	OWN	Dated September 10, 2002
			Monsanto Company	OWN	Dated August 19, 1999
			Signature		Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.

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Date: February 20, 2003			EPA Reg. No./File Symbol: 524-LEI		Page 11 of 14
Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005			Product: Corn Event MON 863		
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated August 19, 1999
			Monsanto Company	OWN	Dated June 20, 2000
			Monsanto Company	OWN	Dated September 10, 2002
			Monsanto Company	OWN	Dated January 13, 2000
			Monsanto Company	OWN	Dated February 20, 2001
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 20, 2003	

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Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated February 20, 2001
			Monsanto Company	OWN	Dated March 20, 2001
			Monsanto Company	OWN	Dated May 21, 2001
			Monsanto Company	OWN	Dated November 5, 2001
			Monsanto Company	OWN	Dated November 5, 2001
			Monsanto Company	OWN	Dated November 5, 2001
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.		Date February 20, 2003

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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated January 8, 2002
			Monsanto Company	OWN	Dated April 9, 2002
			Monsanto Company	OWN	Dated April 9, 2002
			Monsanto Company	OWN	Dated June 10, 2002
			Monsanto Company	OWN	Dated November 23, 1993
			Signature		

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Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated November 23, 1993
			Monsanto Company	OWN	Dated November 23, 1992
			Monsanto Company	PL	Dated November 23, 1993
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 20, 2003	

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CONFIDENTIAL STATEMENT OF FORMULA

{CBI Cross Reference Number 1}

CONFIDENTIAL STATEMENT OF FORMULA

{CBI Cross Reference Number 1}

PRODUCT LABEL

Five copies of the proposed label for 'Corn Event MON 863: Rootworm Protected Corn' are attached. This label supersedes the label previously submitted to EPA, dated February 11, 2003.

Corn Event MON 863: Rootworm Protected Corn

[Alternate brand name: *YieldGard Rootworm*[®]: *Rootworm Protection*]

This product is effective in controlling damage caused by corn rootworm larval feeding on corn roots.

Active Ingredient:

Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary for its production (ZMIR13L) in event MON 863 corn.....0.001 - 0.006%

Other Ingredients:

Substance produced by a marker gene and the genetic material necessary for its production (ZMIR13L) in event MON 863 corn.....0.00002 - 0.00003%

Percentage (wt/wt) on a dry weight basis.

Keep Out of Reach of Children

CAUTION

® YieldGard Rootworm is a trademark of Monsanto Technology LLC

EPA Registration No. 524-528

EPA Establishment No. 524-MO-002

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700 Chesterfield Parkway West
St. Louis, MO 63017

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling.

The following information regarding commercial production must be included in the Event MON 863 Technology Use Guide.

Insect Resistance Management

Growers of Corn Event MON 863: Rootworm Protected Corn must adhere to the following refuge requirements. Growers must plant a structured refuge of at least 20% non-Event MON 863 corn.

Refuge planting options include: adjacent blocks or in-field strips. If blocks are implemented they must be adjacent to the Corn Event MON 863 field. If in-field strips within a corn field are implemented, then at least 6, and preferably 12 consecutive rows should be planted with non-event MON 863 corn.

The refuge and Corn Event MON 863 acres should be managed under comparable agronomic regimes. Refuge and Corn Event MON 863 acres should both be irrigated if irrigation is used. In regions where corn is cropped continuously, refuge and Corn Event MON 863 acres should be planted in a continuous cropping regime. The refuge may be placed only on first-year corn acres if the Event MON 863 corn is planted on first-year corn acres.

Growers have the option of applying conventional insecticides to the corn refuge for control of corn rootworm larvae. Growers are not permitted to apply agents for control of adult corn rootworm to the refuge as this would render the refuge less effective. If growers opt to treat for other insects present in the refuge while adult corn rootworm are present, then the Corn Event MON 863 acres must be treated in a like manner.

These refuge requirements do not apply to operations engaged in the propagation of inbred seed corn.

Corn Insects Controlled or Suppressed

Corn has been genetically transformed to produce the *B.t.* protein, Cry3Bb1, for control or suppression of the following coleopteran insects:

- Western corn rootworm (*Diabrotica virgifera virgifera*)
- Northern corn rootworm (*Diabrotica barberi*)
- Mexican corn rootworm (*Diabrotica virgifera zea*)

CONFIDENTIAL ATTACHMENT

MONSANTO



Amendment of the Application to Register a *Bacillus thuringiensis*
Cry3Bb1 Protein and the Genetic Material Necessary for its
Production (Vector ZMIR13L) in Event MON 863 Corn;
EPA File Symbol 524-LEI

CONFIDENTIAL ATTACHMENT

AUTHOR

Dennis P. Ward, Ph.D.
Regulatory Affairs Manager

DATE

February 20, 2003

SUBMITTING REGISTRANT

Monsanto Company
600 13th Street N.W.
Suite 660
Washington, DC 20005

MONSANTO REFERENCE No.

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CONFIDENTIAL BUSINESS INFORMATION

CBI Cross Reference Number 1

This cross reference number noted on a place holder page is used in place of the following whole page at the indicated volume and page references

The deleted Page is attached immediately behind this page.

<u>Pages</u>	<u>Reason for Deletion</u>	<u>FIFRA Reference</u>
37 & 38	Discloses commercial information	§10(d)(1)(A), (B) or (C)

Registration # 524-528
Volume 4 of 4

Page ___ is not included in this copy.

Pages 126 through 127 are not included in this copy.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
- ☐ Identity of product inert impurities.
- ☐ Description of the product manufacturing process.
- ☐ Description of quality control procedures.
- ☐ Identity of the source of product ingredients.
- ☐ Sales or other commercial/financial information.
- ☐ A draft product label.
- ☒ The product confidential statement of formula.
- ☐ Information about a pending registration action.
- ☐ FIFRA registration data.
- ☐ The document is a duplicate of page(s) _____.
- ☐ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.



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Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005		Product: Corn Event MON 863			
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151-20, 151-21, 151-25 885.1100 885.1200 885.1500	Administrative Materials for Amendment of Application to Registrant of a <i>Bacillus thuringiensis</i> Cry3Bb1 Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in Corn Event MON 863; EPA File Symbol LEI-524.	455770-00	Monsanto Company	OWN	Dated January 8, 2002
151-20, 153-4 885.1100 885.2200	Holleschak, G., R.E. Hileman and J.D. Astwood (2001). Immuno-detectability of NPTII Protein in the Grain of Insect Protected Corn Event MON 863 After Heat Treatment. MSL-17300.	455382-09	Monsanto Company	OWN	Dated November 5, 2001
151-20, 151-21, 151-22, 151-26 885.1100 885.1200 885.1300 885.2100	Cavato, T.A., E.C. Rigden, D.W. Mitanek and R.P. Lirette (2001). Amended Report for MSL-16505: Molecular Analysis of Corn Event MON 863. MSL-17152.	454240-02	Monsanto Company	OWN	Dated May 21, 2001
151-20, 153-4 885.1100 885.2200	Holleschak, G., R.E. Hileman and J.D. Astwood (2001). Amended Report for MSL-16597: Immunodetectability of Cry3Bb1.11098 and Cry3Bb1.11231 Proteins in the Grain of Insect Protected Corn Events MON 863 and MON 863 After Heat Treatment. MSL-17223.	454240-07	Monsanto Company	OWN	Dated May 21, 2001
151-23, 151-25, 153-4, 151-26, 885.1400, 885.1500 885.2200 885.2400 885.2500	Dudin, Y.A., B-P. Tonnu, L.D. Albee and R.P. Lirette (2001). Amended Report for MSL-16559: B.t. Cry3Bb1.11098 and NPTII Protein Levels in Sample Tissue Collected from Corn Event MON 863 Grown in 1999 Field Trials. MSL-171811.	454240-01	Monsanto Company	OWN	Dated May 21, 2001
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 20, 2003	

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Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005		Product: Corn Event MON 863			
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151-26 885.2100	Administrative Materials in Support of the Registration of <i>Bacillus thuringiensis</i> Cry3Bb Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in Corn; and Amendment of the Previous Request for Exemption from the Requirement of a Tolerance. DATE 1999	451568-00	Monsanto Company	OWN	Dated June 20, 2000
151-26 885.2100	Petition from the Requirement of a Tolerance for <i>Bacillus thuringiensis</i> Cry1, Cry2, and Cry3 Classes of Proteins and the Genetic Material Necessary for the Production of These Proteins In or On All Raw Agricultural Commodities When used as Plant-Pesticide Active DATE 1999	PP 7P4888	Monsanto Company	OWN	Dated June 24, 1997
151-26 885.2100	Pilacinski, W. P. and M. W. Taylor (1999). Administrative Materials in Support of the Registration of the Plant-Expressed Protectant <i>Bacillus thuringiensis</i> Corn Rootworm Control Protein, as Produced in the Corn (<i>Zea mays</i> , L.), and the Amendment to the Previous Request for Exemption from the Requirement of a Tolerance.	449043-00	Monsanto Company	OWN	Dated August 19, 1999
151-26 885.2100	Hileman, R.E. and J.D. Astwood (2001). Additional Characterization of the Cry3Bb1 Protein Produced in Corn Event MON 863. MSL-17137.	454240-10	Monsanto Company	OWN	Dated May 21, 2001
151-26 885.2100	Thoma, R.S., G. Holleschak, R.E. Hileman and J.D. Astwood (2001). Primary Structural Protein Characterization of Corn Event MON 863 Cry3Bb1.11098 Protein Using N-terminal Sequencing and MALDI Time of Flight Mass Spectrometric Techniques. MSL-17154	454240-11	Monsanto Company	OWN	Dated May 21, 2001
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 20, 2003	

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Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151-26 885.2100	Hileman, R.E., G. Holleschak, L.A. Turner, R.S. Thoma, C.R. Brown and J.D. Astwood (2001). Characterization and Equivalence of the Cry3Bb1 Protein Produced by <i>E. coli</i> Fermentation and Corn Event MON 863. MSL-17274.	455382-01	Monsanto Company	OWN	Dated November 5, 2001
151-36 885.2200	Hileman, R.E., E.A. Rice, R.E. Goodman and J.D. Astwood (2001). Bioinformatics Evaluation of the Cry3Bb1 Protein Produced in Corn Event MON 863 Utilizing Allergen, Toxin and Public Domain Protein Databases. MSL-17140.	454240-08	Monsanto Company	OWN	Dated May 21, 2001
885.2250	Not applicable since feed residues of Cry3Bb1 protein are not of toxicological concern and there is no requirement for a tolerance in animal tissues.				
151-25 885.2300	D. Kolwyck, B-P. Tonnu, Y. A. Dudin, T. Ploesser and K. Gustafson (2001). Validated Method for Extraction and Direct ELISA Analysis of Cry3Bb1 in Corn Grain.	453731-01	Monsanto Company	OWN	Dated April 7, 2001
885.2350	Not applicable since there is no need for a Cry3Bb1 tolerance in animal tissues.				
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.		Date February 20, 2003

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Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151-27 885.2400	<i>Samples</i> Stability data will be submitted as part of the independent laboratory method validation work that is ongoing.				
153-4 885.2500	Dudin, Y.A., B.P. Torun, L.D. Albee and R.P. Lirette (2001). Amended Report for MSL-16559: <i>B.t.</i> Cry3Bb1.11098 and NPTII Protein Levels in Sample Tissue Collected from Corn Event MON 863 Grown in 1999 Field Trials. MSL-171811.	454240-01	Monsanto Company	OWN	Dated May 21, 2001
885.2550	Not applicable since there is no need for a Cry3Bb1 tolerance in animal tissues.				
885.2600	Not applicable since there are not expected to be any water residues of toxicological concern.				
885.2600 154-19	McKee, M.J. (2001) Bluegill Dietary Toxicity Study for the <i>Bacillus thuringiensis</i> Cry3Bb1 Protein Variant: A Waiver Request. MSI-17383.	455382-00	Monsanto Company	OWN	Dated November 5, 2001
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.		Date February 20, 2003

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Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
152-30 885.3050	Astwood, J.D., R.E. Hileman, M.J. McKee, T.J. Rydel, J.W. Seale and L. English (2001). Safety Assessment of Cry3Bb1 Variants in Corn Rootworm Protected Corn, MSL-17225. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	454240-09	Monsanto Company	OWN	Dated May 21, 2001
152-30 885.3050 885.4150	Bonnette, K.L. and P.D. Pyla (2001). An Acute Oral Toxicity Study in Mice with <i>E. coli</i> Produced Cry3Bb1.11098(Q349R) Protein. Amended Final Report. MSL-17382. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455382-02	Monsanto Company	OWN	Dated November 5, 2001
152-30 885.3050	Leach, J.N., R.E. Hileman and J.D. Astwood (2001). Assessment of the <i>in vitro</i> Digestibility of Cry3Bb1 Protein Purified from Corn Event MON 863 and Cry3Bb1 Protein Purified from <i>E. coli</i> . MSL-17292. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455382-03	Monsanto Company	OWN	Dated November 5, 2001
152-30 885.3050	Hileman, R.E., J.N. Leach and J.D. Astwood (2001). Assessment of the <i>in vitro</i> Digestibility of Cry3Bb1.11098(Q349R) Protein in Simulated Intestinal Fluid. MSL-17530. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455770-02	Monsanto Company	OWN	Dated January 8, 2002
152-31 152-34 152-35 885.3100	Not applicable since Cry3Bb1 is a plant-incorporated active ingredient, is present at low levels, and there is little opportunity for dermal or ocular contact.				
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 20, 2003	

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DATA MATRIX

Date: February 20, 2003			EPA Reg. No./File Symbol: 524-LEI		Page 6 of 16
Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005			Product: Corn Event MON 863		
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
152-32 885.3150	Not applicable since Cry3Bb1 is a plant-incorporated active ingredient, is present at low levels, and there is little opportunity for human inhalation exposure. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.				
152-33 885.3200	Not applicable since Cry3Bb1 protein is neither infective nor pathogenic.				
152-37 152-38 885.3400	There is no clear published evidence that has demonstrated clinical allergic reactions to <i>Bt</i> crystal proteins. Monitoring for hypersensitivity incidents can be implemented after registration is granted.				
152-39 885.3500	Not applicable since Cry3Bb1 is not a virus.				
152-42 885.3600	Not applicable since Cry3Bb1 is plant-incorporated, is present at low levels in corn grain, and is rapidly degraded in the digestive tracks of mammals.				
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.		Date February 20, 2003

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DATA MATRIX

Date: February 20, 2003			EPA Reg. No./File Symbol: 524-LEI		Page 7 of 16
Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005			Product: Corn Event MON 863		
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.3650	Not applicable since Cry3Bb1 is plant-incorporated, is present at low levels in corn grain, and is rapidly degraded in the digestive tracks of mammals.				
154-16 885.4050	Gallagher, S.P., J. Grimes and J.B. Beavers (1999). <i>Bacillus thuringiensis</i> Protein 11231 in Corn Grain: A Dietary Toxicity Study with the Northern Bobwhite. MSL-16161. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-15	Monsanto Company	OWN	Dated August 19, 1999
154-17 885.4100	Not applicable since Cry3Bb1 is a plant-incorporated living organism, is present at low levels and there is little opportunity for avian inhalation exposure. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.				
154-18 885.4150	Not applicable since there is no reason to suspect that wild mammals would be any more sensitive to Cry3Bb1 than laboratory mammals. Mammals do not possess Cry protein receptors. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.				
154-19 885.4200	Li, M.H. and E.H. Robinson (1999). Evaluation of Insect Protected Corn Lines MON 853 and MON 859 as a Feed Ingredient for Catfish. MSL-16164. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-19	Monsanto Company	OWN	Dated August 19, 1999
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Date: February 20, 2003			EPA Reg. No./File Symbol: 524-LEI		Page 8 of 16
Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005			Product: Corn Event MON 863		
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-20 885.4240	Drottler, K.R. and H.O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11098 in Corn Pollen: 48-Hour Static Renewal Acute Toxicity Test with the Cladoceran (<i>Daphnia magna</i>). MSL-15988. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-18	Monsanto Company	OWN	Dated August 19, 1999
154-21 885.4280	Corn is not typically grown in close proximity to estuarine or marine environments. Pollen drift into these environments would not result in water residues of toxicological concern. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.				
154-22 885.4300	<i>Elm 1000</i> Not applicable since Cry3Bb1 is plant-incorporated and not 'applied' to crops.				
154-23 885.4340	Palmer, S.J. and H.O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11231: Dietary Toxicity Study with the Ladybird Beetle (<i>Hippodamia convergens</i>). MSL-16166. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-14	Monsanto Company	OWN	Dated August 19, 1999
154-23 885.4340	Hoxter, K.A., S.J. Palmer and H.O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11231: An Acute Toxicity Study with Earthworm in an Artificial Soil Substrate. MSL-16162. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-16	Monsanto Company	OWN	Dated August 19, 1999
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Date: February 20, 2003		EPA Reg. No./File Symbol: 524-LEI		Page 9 of 16	
Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005		Product: Corn Event MON 863			
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-23 885.4340	Teixeira, D. (1999). Assessment of Chronic Toxicity of Corn Tissue Containing the <i>Bacillus thuringiensis</i> Protein 11098 to Collembola (<i>Folsomia candida</i>). MSL-15988. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-17	Monsanto Company	OWN	Dated August 19, 1999
154-23 885.4340	Palmer, S.J. and H.O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11231: A Dietary Study with Green Lacewing Larvae (<i>Chrysoperla carnea</i>). MSL-16165. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-12	Monsanto Company	OWN	Dated August 19, 1999
154-23 885.4340	Palmer, S.J. and H.O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11231: A Dietary Study with the Parasitic Hymenoptera (<i>Nasonia vitripennis</i>). MSL-1616. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-13	Monsanto Company	OWN	Dated August 19, 1999
154-23 885.4340	Head, G. (2001). Research on the Effects of Corn Rootworm Protected Transgenic Corn Events on Nontarget Organisms: Preliminary Report. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	453484-02	Monsanto Company	OWN	Dated February 20, 2001
154-23 885.4340	Duan, J.J., G. Head, M. McKee and T.E. Nickson (2001). Dietary Effects of Transgenic <i>Bacillus thuringiensis</i> (Bt) Corn Pollen Expressing a Variant of Cry3Bb1 Protein on Adults of the Ladybird Beetle, <i>Coleomegilla maculata</i> . MSL-16936. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	453613-01	Monsanto Company	OWN	Dated March 20, 2001
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Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005		Product: Corn Event MON 863			
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MAID Number	Submitter	Status	Note
154-23 885.4340	Bryan, R.L., J.R. Porch and H.O. Krueger (2001). Dietary Effects of Transgenic BT Corn Pollen Expressing a Variant of Cry3Bb1 Protein on the Ladybird Beetle, <i>Hippodamia convergens</i> . MSL-17171. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	453613-02	Monsanto Company	OWN	Dated March 20, 2001
154-23 885.4340	Bhatti, M.A., C.L. Pilcher, M.J. McKee, T.E. Nickson, G.P. Head and C.D. Pilcher (2001). Field Evaluation for the Ecological Impact of Corn Rootworm Insect-Protected Corn on Non-Target Organisms. MSL-17179. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455382-06	Monsanto Company	OWN	Dated November 5, 2001
154-23 885.4340	Duan, J.J., M.J. McKee and T.E. Nickson (2001). Dietary Effects of Transgenic <i>Bacillus thuringiensis</i> (Bt) Corn Pollen Expressing a Variant of Cry3Bb1 Protein on Larvae of the Ladybird Beetle, <i>Coleomegilla maculata</i> . MSL-16907. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455382-04	Monsanto Company	OWN	Dated November 5, 2001
154-23 885.4340	Sears, M. and M. Mattila (2002). Determination of the Toxicity of Corn Pollen Expressing a Cry3Bb1 Variant Protein to First Instar Monarch Butterfly Larvae (<i>Danux plexippus</i>) via Laboratory Bioassay. MSL-17235. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455382-05	Monsanto Company	OWN	Dated November 5, 2001
154-23 885.4340	Head, G., M. Pleau, S. Sivausupramanian and T. Vaughn (2001). Insecticidal Spectrum of Activity for Cry3Bb Protein <i>in vitro</i> . C3NTO. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455382-07	Monsanto Company	OWN	Dated November 5, 2001
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Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005		Product: Corn Event MON 863			
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-23 885.4340	Duan, J.J., M. J. McKee, G. Head and C.R. Brown (2002). Endangered Species Impact Assessment for Cry3Bb1 Protein in Transgenic Corn Event MON 863. MSL-17614. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455770-03	Monsanto Company	OWN	Dated January 8, 2002
154-23 885.4340	Head, G. (2002). Research on the Effects of Corn Rootworm Protected Transgenic Corn Events on Nontarget Organisms: Preliminary Results. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	456530-03	Monsanto Company	OWN	Dated April 9, 2002
154-23 885.4340	Bhatti, M. A., J. D. Duan, C. L. Pilcher, C. D. Pilcher, M. J. McKee, T. E. Nickson, G. P. Head and C. Jiang (2002). Ecological Assessment of Nontarget Organisms in the Plots of Corn Rootworm Insect Protected Corn Hybrid Containing MON 863 Event: 2000 - 2001 Field Trials. MSL-1461. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.		Monsanto Company	OWN	Dated September 10, 2002
154-23 885.4340	Sindermann, A. B., J. R. Porch and H. O. Krueger (2002). Evaluation of a Cry3Bb1 Protein Variant in an Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate. MSL-18137. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.		Monsanto Company	OWN	Dated September 10, 2002
154-24 885.4380	Maggi, V.L. (1999). Evaluation of the Dietary Effects of Purified <i>Bacillus thuringiensis</i> Protein I1231 on Honey Bee Larvae. MSL-16168. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-10	Monsanto Company	OWN	Dated August 19, 1999
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 20, 2003	

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Date: February 20, 2003			EPA Reg. No./File Symbol: 524-LEI	Page 12 of 16	
Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005			Product: Corn Event MON 863		
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRI/D Number	Submitter	Status	Note
154-24 885.4380	Maggi, V.L. (1999). Evaluation of the Dietary Effect(s) of Purified <i>Bacillus thuringiensis</i> Protein 11231 on Adult Honey Bees (<i>Apis mellifera</i> L.). MSL-16169. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-11	Monsanto Company	OWN	Dated August 19, 1999
154-26 885.4600	Not applicable; no triggers hit for tier III testing. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.				
154-28 885.4700	Not applicable; no triggers hit for tier III testing. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.				
154-29 885.4750	Not applicable since corn is not grown in an aqueous environment. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.				
885.5200	Martin, J.W., M.J. McKee, S. Dubelman and Y.A. Dudin (2000). Aerobic Soil Degradation of the <i>B.t.</i> Protein 11098 as a Component of Insect Protected Corn, MSL-16440; an unpublished study conducted by Monsanto Company.	451568-04	Monsanto Company	OWN	Dated June 20, 2000
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 20, 2003	

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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.5200	Dubelman, S., B. Ayden, M. Mueth, J. A. Warren, C. Jiang, J. Bookout and Y. Dudin (2002). Aerobic Soil Degradation of the <i>Bacillus thuringiensis</i> Cry3Bb1 Variant Protein Produced in Corn Rootworm Protected Corn Event MON 863. MSL-17102.		Monsanto Company	OWN	Dated September 10, 2002
885.5300	Not applicable since corn is not grown in an aqueous environment.				
885.5400	Not applicable since corn is not grown in an aqueous environment.				
	Miller, D. (2000). Public Interest Document Supporting the Registration and Exemption from the Requirement of a Tolerance for the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry3Bb Protein, and the Genetic Material Necessary for its Production in Corn (Vectors ZMIR13L, ZMIR13L and ZMIR13L).	450297-01	Monsanto Company	OWN	Dated January 13, 2000
	Vaughn, T. (2001). Preliminary Results of Research on Insect Resistance Management for a Transgenic Corn Rootworm Control Product.	453484-01	Monsanto Company	OWN	Dated February 20, 2001
Signature			Name and Title Dennis P. Ward, Ph.D Regulatory Affairs Mgr.	Date February 20, 2003	

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Date: February 20, 2003				EPA Reg. No./File Symbol: 524-LEI	Page 14 of 16
Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005				Product: Corn Event MON 863	
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Pilcher, C.D., J.K. McFerson and D.P. Ward (2001). Agronomic Equivalency of Corn Event MON 863 Hybrids as Determined in Year 2000 Field Trials.	453484-03	Monsanto Company	OWN	Dated February 20, 2001
	Pilcher, C.D. (2001). Efficacy of MON 863 Against Corn Rootworm and Comparison to Insecticide Treatments - Results of Year 2000 Field Trials.	453613-03	Monsanto Company	OWN	Dated March 20, 2001
	Administrative Materials in Support of the Application for Registration of Event MON 863: Corn Rootworm Protected Corn (Vector ZMIR13L); EPA File Symbol 524-LEI	454240-00	Monsanto Company	OWN	Dated May 21, 2001
	Administrative Materials in Support of the Application for Registration of Event MON 863: Corn Rootworm Protected Corn (Vector ZMIR13L); EPA File Symbol 524-LEI	455382-00	Monsanto Company	OWN	Dated November 5, 2001
	Vaughn, T.T., M. Pleau, R. Knutson and T. Coombe (2001). Comparing the Efficacy of MON 863 and MON 863 to Three Corn Rootworm Species, Northern Corn Rootworm (<i>Diabrotica barberi</i>), Southern Corn Rootworm (<i>D. undecimpunctata howardi</i>), and Western Corn Rootworm (<i>D. lineolata</i>).	455382-08	Monsanto Company	OWN	Dated November 5, 2001
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DATA MATRIX

Date: February 20, 2003		EPA Reg. No./File Symbol: 524-LEI		Page 15 of 16	
Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005		Product: Corn Event MON 863			
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Vaughn, T., D. Ward, J. Pershing, G. Head and J. McPerson (2001). An Interim Insect Resistance Management Plan for Corn Event MON 863: A Transgenic Corn Rootworm Control Product. MSL-17556.	455770-01	Monsanto Company	OWN	Dated January 8, 2002
	Ward, D. P. (2002). Public Interest Assessment Supporting Registration of <i>Bacillus thuringiensis</i> Cry3Bb1 Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in Corn Event MON 863. MSL-17766.	456530-01	Monsanto Company	OWN	Dated April 9, 2002
	Mitchell, P. D. (2002). Yield Benefit of Corn Event MON 863. MSL-17782.	456530-02	Monsanto Company	OWN	Dated April 9, 2002
	Alston, J. M., J. Hyde and M. C. Marra (2002). An Ex Ante Analysis of the Benefits from the Adoption of Monsanto's Corn Rootworm Resistant Varietal Technology - Yield [®] Rootworm. MSL-17993.	456923-01	Monsanto Company	OWN	Dated June 10, 2002
151.20	Stone, T. (1993). Administrative Materials in Support of the Exemption from the Requirement of a Tolerance for Neomycin Phosphotransferase II as a Plant Pesticide Formulation Inert Ingredient. 93-132E	430547-00	Monsanto Company	OWN	Dated November 23, 1993
Signature			Name and Title Dennis P. Ward, Ph.D Regulatory Affairs Mgr.	Date February 20, 2003	

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DATA MATRIX

Date: February 20, 2003

EPA Reg. No./File Symbol: 524-LEI

Page 16 of 16

Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
152-30	Naylor, M. W. (1992). Acute Oral Toxicity Study of Neomycin Phosphotransferase (NPTII) in Albino Mice. ML-91-409. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	430547-01	Monsanto Company	OWN	Dated November 23, 1993
152-30	Ream, J. E. (1993). Assessment of Degradation of Neomycin Phosphotransferase II in <i>in vitro</i> Mammalian Digestion Models. IRC-91-ANA-06. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	430933-02	Monsanto Company	OWN	Dated November 23, 1993
	Literature Cited in Submission Supporting the Exemption from the Requirement of a Tolerance for the Plant Pesticide Formulation Inert Ingredient Neomycin Phosphotransferase II.	430547-02	PL		Dated November 23, 1993
Signature			Name and Title Dennis P. Ward, Ph.D Regulatory Affairs Mgr.	Date February 20, 2003	

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Dennis P. Ward, Ph.D.
Regulatory Affairs Manager
(636) 737-6631

Monsanto Company
700 Chesterfield Pkwy West
Chesterfield, MO 63017
PHONE (314) 594-1000
FAX (636) 737-5943
<http://www.monsanto.com>

February 14, 2003

Janet L. Andersen, Ph.D. (7511C)
Director, Biopesticides and Pollution Prevention Division
Office of Pesticides Programs
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Subj: Monsanto acceptance of terms and conditions for registration of MON 863
Response to your letter of February 14, 2003

Dear Dr. Andersen:

Monsanto has carefully reviewed the contents of the Agency's MON 863 Cry3Bb1 Corn Pre-acceptance letter, dated February 14, 2003, and agrees to all terms and conditions set forth in this letter. In addition, we have submitted revised labeling that conforms to the refuge requirements as specified in said pre-acceptance letter.

As indicated, it is Monsanto's intention to submit within 60 days a petition to convert the Cry3Bb1 time-limited tolerance exemption to a nonexpiring tolerance exemption. At the same time we will also be submitting an application to extend the length of the registration.

Should you have any questions regarding our response please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (636-737-6631).

Sincerely,

Dennis P. Ward, Ph.D.
Regulatory Affairs Manager

cc: Russell Schneider, Monsanto

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B

Dennis P. Ward, Ph.D.
Regulatory Affairs Manager
(636) 737-6631

Monsanto Company
700 Chesterfield Pkwy West
Chesterfield, MO 63017
PHONE (314) 694-1000
FAX (636) 737-5943
<http://www.monsanto.com>

February 13, 2003

Document Processing Desk (APPL)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Attn: Phillip O. Hutton, Team Leader 90

Subj: Amendment to application for registration of Corn Event MON 863
EPA File Symbol 524-LEI

Dear Mr. Hutton:

In response to a request received from Mr. Mike Mendelsohn, we are providing a revised data matrix, label and Confidential Statement of Formula for Corn Event MON 863.

Enclosed with this submission are the following materials:

- Application for Pesticide (EPA Form 8570-1)
- Certification with Respect to Citation of Data (EPA Form 8570-34)
- Data Matrix (EPA Form 8570-35)
- Product label (5 copies)
- Confidential attachment

Except for the materials contained in the confidential attachment, Monsanto does not object to placement of materials contained in this submission in the Public Docket.

Should you require any additional information regarding this submission please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (636-737-6631).

Sincerely,

Dennis P. Ward, Ph.D.
Regulatory Affairs Manager

Mr. P. Hutton
2/11/2003
Page 2 of 49

Att: Administrative materials

cc: Mike Mendelsohn, EPA/OPP/BPPD
Russell Schneider, Monsanto



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier
Number

Application for Pesticide – Section I

1. Company/Product Number File Symbol 524-LEI	2. EPA Product Manager Phillip O. Hutton	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
Company/Product (Name) Corn Event MON 863	PM # 90	
5. Name and Address of Applicant (Include ZIP Code) Monsanto Company 600 13 th St., N.W., Suite 660 Washington, DC 20005 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section – II

<input checked="" type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated
<input type="checkbox"/> Resubmission in response to Agency letter dated	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification – Explain below.	<input type="checkbox"/> Other – Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Submission of revised data matrix, labeling and CSF

Section – III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted		If "Yes" Unit Packaging-wgt. No. per Container	If "Yes" Package wgt. No. per Container	<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other	(Specify)
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Other <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

Section – IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Russell P. Schneider		Title Regulatory Affairs Director		Telephone No. (Include Area Code) (202) 383-2866	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped) 147
2. Signature 		3. Title Regulatory Affairs Manager			
4. Typed Name Dennis P. Ward Tel. (636) 737-6631		5. Date February 13, 2003			

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WASHINGTON, D.C. 20460**

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number: Monsanto Company, 600 13 th Street, N.W., Washington, DC 2005 (202) 383-2866	EPA Registration Number / File Symbol: 524-LEI
Active Ingredient(s) and/or representative test compound(s): <i>B.t. Cry3Bb1 and the genetic material necessary for its production (vector ZMIR13L) in event MON 863 corn</i>	Date: February 13, 2003
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158: Terrestrial field crop	Product Name: Corn Event MON 863

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-in Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

Section I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
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Section II: GENERAL OFFER TO PAY

☐ [Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]
I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

Section III: CERTIFICATION


I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-in response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under the applicable law.

Signature 	Date February 13, 2003	Typed or Printed Name and Title Dennis P. Ward, Regulatory Affairs Manager
--	---------------------------	---

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DATA MATRIX

Date: February 13, 2003		EPA Reg. No./File Symbol: 524-LEI		Page 1 of 16	
Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005		Product: Corn Event MON 863			
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151-20, 151-21, 151-25 885.1100 885.1200 885.1500	Administrative Materials for Amendment of Application to Registrant of a <i>Bacillus thuringiensis</i> Cry3Bb1 Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in Corn Event MON 863; EPA File Symbol LEI-524.	455770-00	Monsanto Company	OWN	Dated January 8, 2002
151-20, 153-4 885.1100 885.2200	Holleschak, G., R.E. Hileman and J.D. Astwood (2001). Immuno-detectability of NPTII Protein in the Grain of Insect Protected Corn Event MON 863 After Heat Treatment. MSL-17300; an unpublished study conducted by Monsanto Company.	455382-09	Monsanto Company	OWN	Dated November 5, 2001
151-20, 151-21, 151-22, 151-26 885.1100 885.1200 885.1300 885.2100	Cavato, T.A., E.C. Rigden, D.W. Mitanck and R.P. Lirette (2001). Amended Report for MSL-16505: Molecular Analysis of Corn Event MON 863. MSL-17152; an unpublished study conducted by Monsanto Company.	454240-02	Monsanto Company	OWN	Dated May 21, 2001
151-20, 153-4 885.1100 885.2200	Holleschak, G., R.E. Hileman and J.D. Astwood (2001). Amended Report for MSL-16597: Immunodetectability of Cry3Bb1.11098 and Cry3Bb1.11231 Proteins in the Grain of Insect Protected Corn Events MON 863 and MON 853 After Heat Treatment. MSL-17223; an unpublished study conducted by Monsanto Company.	454240-07	Monsanto Company	OWN	Dated May 21, 2001
151-23, 151-25, 153-4, 151-26, 885.1400, 885.1500, 885.2200 885.2400 885.2500	Dudin, Y.A., B-P. Tonnu, L.D. Aibee and R.P. Lirette (2001). Amended Report for MSL-16559: <i>B.t.</i> Cry3Bb1.11098 and NPTII Protein Levels in Sample Tissue Collected from Corn Event MON 863 Grown in 1999 Field Trials. MSL-171811; an unpublished study conducted by Monsanto Company.	454240-01	Monsanto Company	OWN	Dated May 21, 2001
Signature 			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.		Date February 13, 2003

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DATA MATRIX

Date: February 13, 2003		EPA Reg. No./File Symbol: 524-LEI		Page 2 of 16	
Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005		Product: Corn Event MON 863			
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151-26 885.2100	Administrative Materials in Support of the Registration of <i>Bacillus thuringiensis</i> Cry3Bb Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in Corn; and Amendment of the Previous Request for Exemption from the Requirement of a Tolerance. PP7E4928	451568-00	Monsanto Company	OWN	Dated June 20, 2000
151-26 885.2100	Petition from the Requirement of a Tolerance for <i>Bacillus thuringiensis</i> Cry1, Cry2, and Cry3 Classes of Proteins and the Genetic Material Necessary for the Production of These Proteins In or On All Raw Agricultural Commodities When used as Plant-Pesticide Active Ingredients	PP 7F4888	Monsanto Company	OWN	Dated June 24, 1997
151-26 885.2100	Pilacinski, W. P. and M. W. Taylor (1999). Administrative Materials in Support of the Registration of the Plant-Expressed Protectant <i>Bacillus thuringiensis</i> Corn Rootworm Control Protein, as Produced in the Corn (<i>Zea mays</i> , L.), and the Amendment to the Previous Request for Exemption from the Requirement of a	449043-00	Monsanto Company	OWN	Dated August 19, 1999
151-26 885.2100	Hileman, R.E. and J.D. Astwood (2001). Additional Characterization of the Cry3Bb1 Protein Produced in Corn Event MON 863. MSL-17137; an unpublished study conducted by Monsanto Company.	454240-10	Monsanto Company	OWN	Dated May 21, 2001
151-26 885.2100	Thoma, R.S., G. Holleschak, R.E. Hileman and J.D. Astwood (2001). Primary Structural Protein Characterization of Corn Event MON 863 Cry3Bb1.11098 Protein Using N-terminal Sequencing and MALDI Time of Flight Mass Spectrometric Techniques. MSL-17154; an unpublished study	454240-11	Monsanto Company	OWN	Dated May 21, 2001
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 13, 2003	

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Date: February 13, 2003

EPA Reg. No./File Symbol: 524-LEI

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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151-26 885.2100	Hileman, R.E., G. Holleschak, L.A. Turner, R.S. Thoma, C.R. Brown and J.D. Astwood (2001). Characterization and Equivalence of the Cry3Bb1 Protein Produced by <i>E. coli</i> Fermentation and Corn Event MON 863. MSL-17274; an unpublished study conducted by Monsanto Company.	455382-01	Monsanto Company	OWN	Dated November 5, 2001
151-36 885.2200	Hileman, R.E., E.A. Rice, R.E. Goodman and J.D. Astwood (2001). Bioinformatics Evaluation of the Cry3Bb1 Protein Produced in Corn Event MON 863 Utilizing Allergen, Toxin and Public Domain Protein Databases. MSL-17140; an unpublished study conducted by Monsanto Company.	454240-08	Monsanto Company	OWN	Dated May 21, 2001
153-4 885.2250	Not applicable since feed residues of Cry3Bb1 protein are not of toxicological concern and there is no requirement for a tolerance in animal tissues.				
151-25 885.2300	D. Kolwyck, B-P. Tonnu, Y. A. Dudin, T. Ploesser and K. Gustafson (2001). Validated Method for Extraction and Direct ELISA Analysis of Cry3Bb1 in Corn Grain. An unpublished report prepared by Monsanto Company.	453731-01	Monsanto Company	OWN	Dated April 7, 2001
151-25 885.2350	Not applicable since there is no need for a Cry3Bb1 tolerance in animal tissues.				
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 13, 2003	

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Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005		Product: Corn Event MON 863			
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151-27 885.2400	Storage stability data will be submitted as part of the independent laboratory method validation work that is ongoing.				
153-4 885.2500	Dudin, Y.A., B-P. Tonnu, L.D. Alhee and R.P. Lirette (2001). Amended Report for MSL-16559: <i>B.t.</i> Cry3Bb1.11098 and NPTII Protein Levels in Sample Tissue Collected from Corn Event MON 863 Grown in 1999 Field Trials. MSL-171811: an unpublished study conducted by Monsanto Company.	454240-01	Monsanto Company	OWN	Dated May 21, 2001
153-4 885.2550	Not applicable since there is no need for a Cry3Bb1 tolerance in animal tissues.				
153-4 885.2600	Not applicable since there are not expected to be any water residues of toxicological concern.				
153-4 885.2600	McKee, M.J. (2001) Bluegill Dietary Toxicity Study for the <i>Bacillus thuringiensis</i> Cry3Bb1 Protein Variant: A Waiver Request. MSL-17383; an analysis conducted by Monsanto Company.	455382-00	Monsanto Company	OWN	Dated November 5, 2001
Signature: 152			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 13, 2003	

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Date: February 13, 2003			EPA Reg. No./File Symbol: 524-LEI		Page 5 of 16
Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005			Product: Corn Event MON 863		
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
152-30 885.3050	Astwood, J.D., R.E. Hileman, M.J. McKee, T.J. Rydel, J.W. Scale and L. English (2001). Safety Assessment of Cry3Bb1 Variants in Corn Rootworm Protected Corn. MSL-17225; an unpublished analysis prepared by Monsanto Company.	454240-09	Monsanto Company	OWN	Dated May 21, 2001
152-30 885.3050 885.4150	Bonnette, K.L. and P.D. Pyla (2001). An Acute Oral Toxicity Study in Mice with <i>E. coli</i> Produced Cry3Bb1.11098(Q349R) Protein. Amended Final Report. MSL-17382; an unpublished study conducted for Monsanto Company.	455382-02	Monsanto Company	OWN	Dated November 5, 2001
152-30 885.3050	Leach, J.N., R.E. Hileman and J.D. Astwood (2001). Assessment of the <i>in vitro</i> Digestibility of Cry3Bb1 Protein Purified from Corn Event MON 863 and Cry3Bb1 Protein Purified from <i>E. coli</i> . MSL-17292; an unpublished study conducted by Monsanto Company.	455382-03	Monsanto Company	OWN	Dated November 5, 2001
152-30 885.3050	Hileman, R.E., J.N. Leach and J.D. Astwood (2001). Assessment of the <i>in vitro</i> Digestibility of Cry3Bb1.11098(Q349R) Protein in Simulated Intestinal Fluid. MSL-17530; an unpublished study conducted by Monsanto Company.	455770-02	Monsanto Company	OWN	Dated January 8, 2002
152-31 152-34 152-35 885.3100	Not applicable since Cry3Bb1 is a plant-incorporated active ingredient, is present at low levels, and there is little opportunity for dermal or ocular contact.				
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.		Date February 13, 2003

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Date: February 13, 2003		EPA Reg. No./File Symbol: 524-LEI		Page 6 of 16	
Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005		Product: Corn Event MON 863			
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
152-32 885.3150	Not applicable since Cry3Bb1 is a plant-incorporated active ingredient, is present at low levels, and there is little opportunity for human inhalation exposure.				
152-33 885.3200	Not applicable since Cry3Bb1 protein is neither infective nor pathogenic.				
152-37 152-38 885.3400	There are no documented reports of hypersensitivity reactions to <i>Bt</i> microbial formulations or proteins; McClintock <i>et al.</i> , (1995) <i>Pestic. Sci.</i> 45:95-105.			PL	
152-39 885.3500	Not applicable since Cry3Bb1 is not a virus.				
152-42 885.3600	Not applicable since Cry3Bb1 is plant-incorporated, is present at low levels in corn grain, and is rapidly degraded in the digestive tracks of animals.				
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 13, 2003	

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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.3650	Not applicable since Cry3Bb1 is plant-incorporated, is present at low levels in corn grain, and is rapidly degraded in the digestive tracks of mammals.				
154-16 885.4050	Gallagher, S.P., J. Grimes and J.B. Beavers (1999). <i>Bacillus thuringiensis</i> Protein 11231 in Corn Grain: A Dietary Toxicity Study with the Northern Bobwhite. MSL-16161; an unpublished study conducted for Monsanto Company.	449043-15	Monsanto Company	OWN	Dated August 19, 1999
154-17 885.4100	Not applicable since Cry3Bb1 is a plant-incorporated active ingredient, is present at low levels, and there is little opportunity for avian inhalation exposure.				
154-18 885.4150	Not applicable since there is no reason to suspect that wild mammals would be any more sensitive to Cry3Bb1 than laboratory mammals. Mammals do not possess Cry protein receptors.				
154-19 885.4200	L. M.H. and E.H. Robinson (1999). Evaluation of Insect Protected Corn Lines MON 853 and MON 859 as a Feed Ingredient for Catfish. MSL-16164; an unpublished study conducted for Monsanto Company.	449043-19	Monsanto Company	OWN	Dated August 19, 1999
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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-20 885.4240	Drottar, K.R. and H.O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11098 in Corn Pollen: 48-Hour Static Renewal Acute Toxicity Test with the Cladoceran (<i>Daphnia magna</i>). MSL-15988; an unpublished study conducted for Monsanto Company.	449043-18	Monsanto Company	OWN	Dated August 19, 1999
154-21 885.4280	Not applicable since corn is not grown in close proximity to estuarine or marine environments.				
154-22 885.4300	Not applicable since Cry3Bb1 is plant-incorporated and not 'applied' to crops.				
154-23 885.4340	Palmer, S.J. and H.O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11231: Dietary Toxicity Study with the Ladybird Beetle (<i>Hippodamia convergens</i>). MSL-16166; an unpublished study conducted for Monsanto Company.	449043-14	Monsanto Company	OWN	Dated August 19, 1999
154-23 885.4340	Foxter, K.A., S.J. Palmer and H.O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11231: An Acute Toxicity Study with Earthworm in an Artificial Soil Substrate. MSL-16162; an unpublished study conducted for Monsanto Company.	449043-16	Monsanto Company	OWN	Dated August 19, 1999
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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient: *Bacillus thuringiensis* Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-23 885.4340	Teixeira, D. (1999). Assessment of Chronic Toxicity of Corn Tissue Containing the <i>Bacillus thuringiensis</i> Protein 11098 to <i>Collembola</i> (<i>Folsomia candida</i>). MSL-15988; an unpublished study conducted for Monsanto Company.	449043-17	Monsanto Company	OWN	Dated August 19, 1999
154-23 885.4340	Palmer, S.J. and H.O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11231: A Dietary Study with Green Lacewing Larvae (<i>Chrysoperla carnea</i>). MSL-16165; an unpublished study conducted for Monsanto Company.	449043-12	Monsanto Company	OWN	Dated August 19, 1999
154-23 885.4340	Palmer, S.J. and H.O. Krueger (1999). <i>Bacillus thuringiensis</i> Protein 11231: A Dietary Study with the Parasitic Hymenoptera (<i>Nasonia vitripennis</i>). MSL-16167; an unpublished study conducted for Monsanto Company.	449043-13	Monsanto Company	OWN	Dated August 19, 1999
154-23 885.4340	Head, G. (2001). Research on the Effects of Corn Rootworm Protected Transgenic Corn Events on Nontarget Organisms: Preliminary Results. An unpublished report prepared by Monsanto Company.	453484-02	Monsanto Company	OWN	Dated February 20, 2001
154-23 885.4340	Juan, J.J., G. Head, M. McKee and T.E. Nickson (2001). Dietary Effects of Transgenic <i>Bacillus thuringiensis</i> (Bt) Corn Pollen Expressing a Variant of Cry3Bb1 Protein on Adults of the Ladybird Beetle, <i>Coleomegilla maculata</i> . MSL-16936; an unpublished study conducted by Monsanto Company.	453613-01	Monsanto Company	OWN	Dated March 20, 2001
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Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-23 885.4340	Bryan, R.L., J.R. Porch and H.O. Krueger (2001). Dietary Effects of Transgenic BT Corn Pollen Expressing a Variant of Cry3Bb1 Protein on the Ladybird Beetle, <i>Hippodamia convergens</i> . MSL-17171; an unpublished study conducted for Monsanto Company.	453613-02	Monsanto Company	OWN	Dated March 20, 2001
154-23 885.4340	Bhatti, M.A., C.L. Pilcher, M.J. McKee, T.E. Nickson, G.P. Head and C.D. Pilcher (2001). Field Evaluation for the Ecological Impact of Corn Rootworm Insect-Protected Corn on Non-Target Organisms. MSL-17179; an unpublished study conducted by Monsanto Company.	455382-06	Monsanto Company	OWN	Dated November 5, 2001
154-23 885.4340	Duan, J.J., M.J. McKee and T.E. Nickson (2001). Dietary Effects of Transgenic <i>Bacillus thuringiensis</i> (Bt) Corn Pollen Expressing a Variant of Cry3Bb1 Protein on Larvae of the Ladybird Beetle, <i>Coleomegilla maculata</i> . MSL-16907; an unpublished study conducted by Monsanto Company.	455382-04	Monsanto Company	OWN	Dated November 5, 2001
154-23 885.4340	Sears, M. and M. Mattila (2002). Determination of the Toxicity of Corn Pollen Expressing a Cry3Bb1 Variant Protein to First Instar Monarch Butterfly Larvae (<i>Danusa plexippus</i>) via Laboratory Bioassay. MSL-17235; an unpublished study conducted for Monsanto Company.	455382-05	Monsanto Company	OWN	Dated November 5, 2001
154-23 885.4340	Head, G., M. Pleau, S. Sivausupramanian and T. Vaughn (2001). Insecticidal Spectrum of Activity for Cry3Bb Protein <i>in vitro</i> . C3NTO; an unpublished study conducted by Monsanto Company.	455382-07	Monsanto Company	OWN	Dated November 5, 2001
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Applicant's/Registrant's Name & Address:
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Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-23 885.4340	Duan, J.J., M. J. McKee, G. Head and C.R. Brown (2002). Endangered Species Impact Assessment for Cry3Bb1 Protein in Transgenic Corn Event MON 863. MSL-17614; an unpublished assessment prepared by Monsanto Company.	455770-03	Monsanto Company	OWN	Dated January 8, 2002
154-23 885.4340	Head, G. (2002). Research on the Effects of Corn Rootworm Protected Transgenic Corn Events on Nontarget Organisms: Preliminary Results. An unpublished report prepared by Monsanto Company.	456530-03	Monsanto Company	OWN	Dated April 9, 2002
154-23 885.4340	Bhatti, M. A., J. D. Duan, C. L. Pilcher, C. D. Pilcher, M. J. McKee, T. E. Nickson, G. P. Head and C. Jiang (2002). Ecological Assessment of Nontarget Organisms in the Plots of Corn Rootworm Insect Protected Corn Hybrid Containing MON 863 Event: 2000 - 2001 Field Trials. Report MSL-17531; an unpublished study conducted by Monsanto Company.		Monsanto Company	OWN	Dated September 10, 2002
154-23 885.4340	Sindermann, A. B., J. R. Porch and H. O. Krueger (2002). Evaluation of a Cry3Bb1 Protein Variant in an Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate. MSL-18137, an unpublished study conducted for Monsanto Company.		Monsanto Company	OWN	Dated September 10, 2002
154-24 885.4380	Maggi, V.L. (1999). Evaluation of the Dietary Effects of Purified <i>Bacillus thuringiensis</i> Protein 11231 on Honey Bee Larvae. MSL-16168; an unpublished study conducted for Monsanto Company.	449043-10	Monsanto Company	OWN	Dated August 19, 1999
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Applicant's/Registrant's Name & Address:

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Product: Corn Event MON 863

Ingredient: *Bacillus thuringiensis* Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-24 885.4380	Maggi, V.L. (1999). Evaluation of the Dietary Effect(s) of Purified <i>Bacillus thuringiensis</i> Protein 11231 on Adult Honey Bees (<i>Apis mellifera</i> L.). MSL-16169; an unpublished study conducted for Monsanto Company.	449043-11	Monsanto Company	OWN	Dated August 19, 1999
154-26 885.4600	Not applicable; no triggers hit for tier III testing.				
154-28 885.4700	Not applicable; no triggers hit for tier III testing.				
154-29 885.4750	Not applicable since corn is not grown in an aqueous environment.				
885.5200	Martin, J.W., M.J. McKee, S. Dubelman and Y.A. Dudin (2000). Aerobic Soil Degradation of the <i>B.t.</i> Protein 11098 as a Component of Insect Protected Corn. MSL-16440; an unpublished study conducted by Monsanto Company.	451568-04	Monsanto Company	OWN	Dated June 20, 2000
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Applicant's/Registrant's Name & Address:

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Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.5200	Dubelman, S., B. Ayden, M. Much, J. A. Warren, C. Jiang, J. Bookout and Y. Dudin (2002). Aerobic Soil Degradation of the <i>Bacillus thuringiensis</i> Cry3Bb1 Variant Protein Produced in Corn Rootworm Protected Corn Event MON 863. MSL-17102, an unpublished study conducted by Monsanto Company.		Monsanto Company	OWN	Dated September 10, 2002
885.5300	Not applicable since corn is not grown in an aqueous environment.				
885.5400	Not applicable since corn is not grown in an aqueous environment.				
	Miller, D. (2000). Public Interest Document Supporting the Registration and Exemption from the Requirement of a Tolerance for the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry3Bb Protein, and the Genetic Material Necessary for its Production in Corn (Vectors ZMIR13L, ZMIR13L and ZMIR14L).	450297-01	Monsanto Company	OWN	Dated January 13, 2000
	Vaughn, T. (2001). Preliminary Results of Research on Insect Resistance Management for a Transgenic Corn Rootworm Control Product. An unpublished report prepared by Monsanto Company.	453484-01	Monsanto Company	OWN	Dated February 20, 2001
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Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Pilcher, C.D., J.K. McFerson and D.P. Ward (2001). Agronomic Equivalency of Corn Event MON 863 Hybrids as Determined in Year 2000 Field Trials. An unpublished study conducted by Monsanto Company.	453484-03	Monsanto Company	OWN	Dated February 20, 2001
	Pilcher, C.D. (2001). Efficacy of MON 863 Against Corn Rootworm and Comparison to Insecticide Treatments - Results of Year 2000 Field Trials. An unpublished study conducted by Monsanto Company.	453613-03	Monsanto Company	OWN	Dated March 20, 2001
	Administrative Materials in Support of the Application for Registration of Event MON 863: Corn Rootworm Protected Corn (Vector ZMIR13L); EPA File Symbol 524-LEI	454240-00	Monsanto Company	OWN	Dated May 21, 2001
	Administrative Materials in Support of the Application for Registration of Event MON 863: Corn Rootworm Protected Corn (Vector ZMIR13L); EPA File Symbol 524-LEI	455382-00	Monsanto Company	OWN	Dated November 5, 2001
	Vaughn, T.T., M. Pleau, R. Knutson and T. Coombe (2001). Comparing the Efficacy of MON 853 and MON 863 to Three Corn Rootworm Species, Northern Corn Rootworm (<i>Diabrotica barberi</i>), Southern Corn Rootworm (<i>D. undecimpunctata howardi</i>), and Western Corn Rootworm (<i>D. virgifera virgifera</i>). MTC RPT 4-00	455382-08	Monsanto Company	OWN	Dated November 5, 2001
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Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MFID Number	Submitter	Status	Note
	Vaughn, T., D. Ward, J. Pershing, G. Head and J. McFerson (2001). An Interim Insect Resistance Management Plan for Corn Event MON 863: A Transgenic Corn Rootworm Control Product. MSL-17556: an unpublished report prepared by Monsanto Company.	455770-01	Monsanto Company	OWN	Dated January 8, 2002
	Ward, D. P. (2002). Public Interest Assessment Supporting Registration of <i>Bacillus thuringiensis</i> Cry3Bb1 Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in Corn Event MON 863. MSL-17766, an unpublished report prepared by Monsanto Company.	456530-01	Monsanto Company	OWN	Dated April 9, 2002
	Mitchell, P. D. (2002). Yield Benefit of Corn Event MON 863. MSL-17782, an unpublished study conducted for Monsanto Company.	456530-02	Monsanto Company	OWN	Dated April 9, 2002
	Alston, J. M., J. Hyde and M. C. Marra (2002). An Ex Ante Analysis of the Benefits from the Adoption of Monsanto's Corn Rootworm Resistant Varietal Technology - Yield Rootworm. Report MSL-17993, an unpublished analysis conducted for Monsanto Company.	456923-01	Monsanto Company	OWN	Dated June 10, 2002
151.20	Stone, T. (1993). Administrative Materials in Support of the Exemption from the Requirement of a Tolerance for Neomycin Phosphotransferase II as a Plant Pesticide Formulation Inert Ingredient. 93-132E	430547-00	Monsanto Company	OWN	Dated November 23, 1993
Signature			Name and Title Dennis P. Ward, Ph.D Regulatory Affairs Mgr.	Date February 13, 2003	

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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
152-30	Naylor, M. W. (1992). Acute Oral Toxicity Study of Neomycin Phosphotransferase (NPTII) in Albino Mice. ML-91-409, an unpublished study conducted by Monsanto Company	430547-01	Monsanto Company	OWN	Dated November 23, 1993
152.30	Ream, J. E. (1993). Assessment of Degradation of Neomycin Phosphotransferase II in <i>In vitro</i> Mammalian Digestion Models. IRC-91-ANA-06, an unpublished study conducted by Monsanto Company	430933-02	Monsanto Company	OWN	Dated November 23, 1993
	Literature Cited in Submission Supporting the Exemption from the Requirement of a Tolerance for the Plant Pesticide Formulation Inert Ingredient Neomycin Phosphotransferase II.	430547-02	PL		Dated November 23, 1993
Signature			Name and Title Dennis P. Ward, Ph.D Regulatory Affairs Mgr.	Date February 13, 2003	

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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient: *Bacillus thuringiensis* Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated January 8, 2002
			Monsanto Company	OWN	Dated November 5, 2001
			Monsanto Company	OWN	Dated May 21, 2001
			Monsanto Company	OWN	Dated May 21, 2001
			Monsanto Company	OWN	Dated May 21, 2001
			Monsanto Company	OWN	Dated May 21, 2001
Signature 			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 13, 2003	

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Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005		Product: Corn Event MON 863			
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated June 20, 2000
			Monsanto Company	OWN	Dated June 24, 1997
			Monsanto Company	OWN	Dated August 19, 1999
			Monsanto Company	OWN	Dated May 21, 2001
			Monsanto Company	OWN	Dated May 21, 2001
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 13, 2003	

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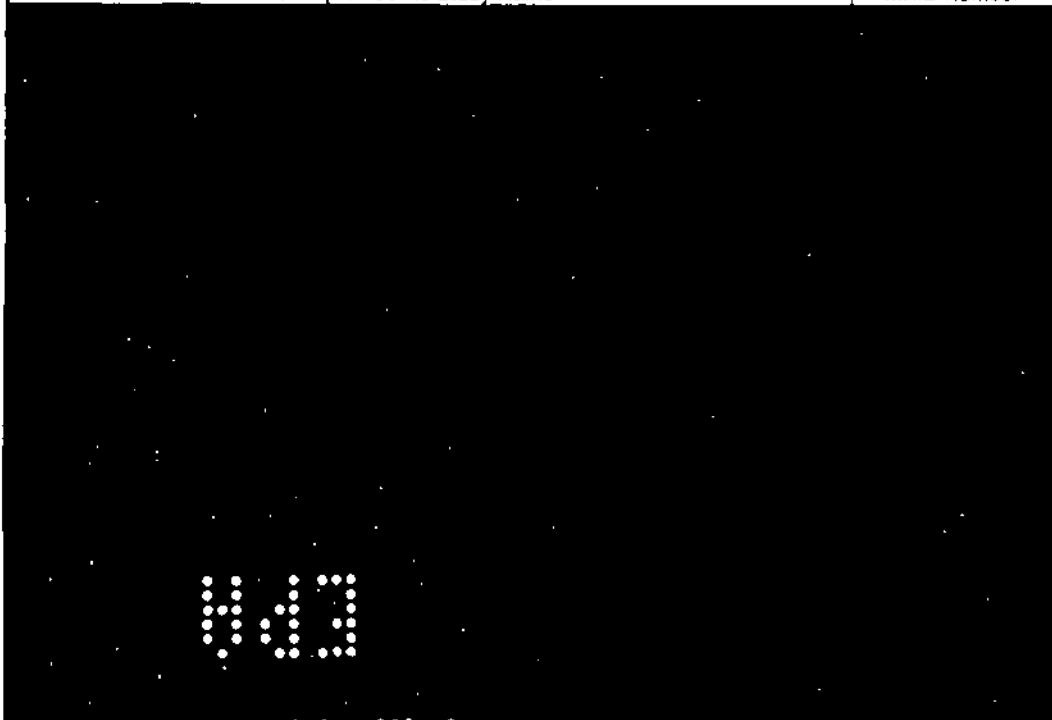
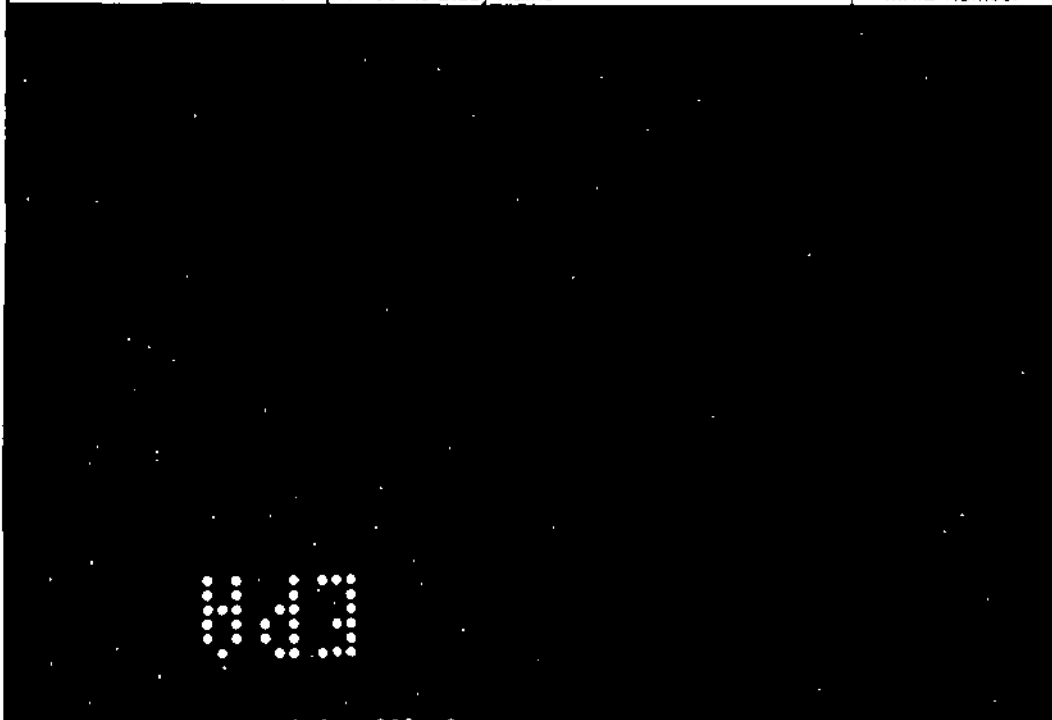
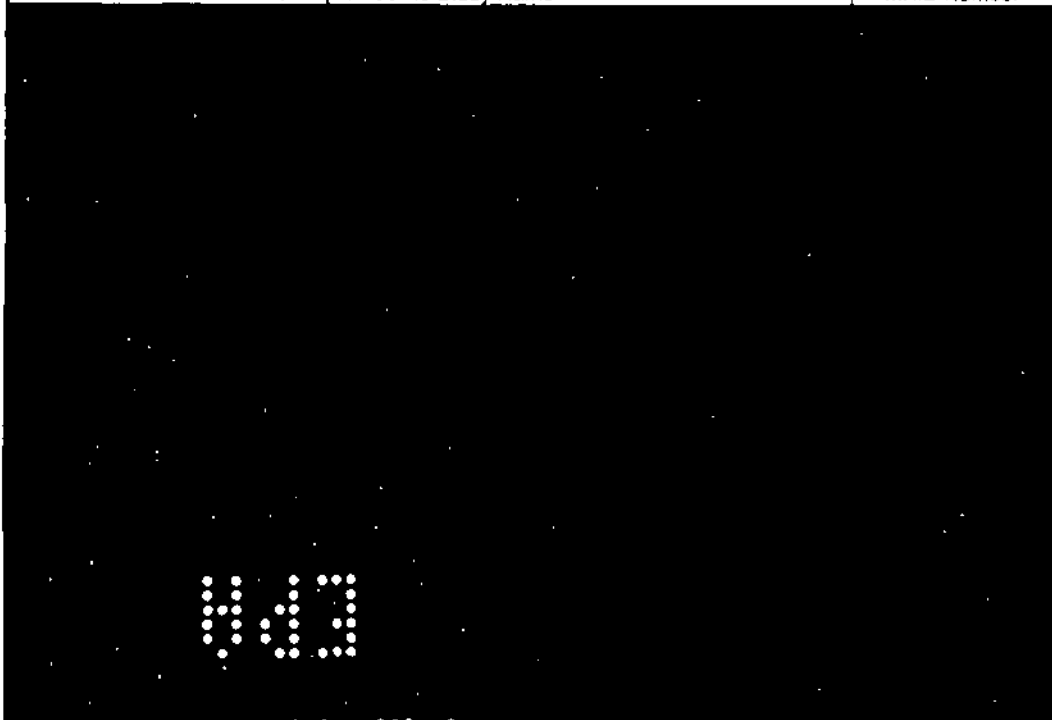
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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated November 5, 2001
			Monsanto Company	OWN	Dated May 21, 2001
			Monsanto Company	OWN	Dated April 7, 2001
			Signature		

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Applicant's/Registrant's Name & Address:

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Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					
			Monsanto Company	OWN	Dated May 21, 2001
			Monsanto Company	OWN	Dated November 5, 2001
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 13, 2003	

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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated May 21, 2001
			Monsanto Company	OWN	Dated November 5, 2001
					Dated November 5, 2001
					Dated January 8, 2002
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 13, 2003	

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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					
				PL	
Signature 			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.		Date February 13, 2003

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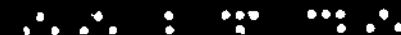
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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					
			Monsanto Company	OWN	Dated August 19, 1999
			Monsanto Company	OWN	Dated August 19, 1999
Signature 			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.		Date February 13, 2003

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Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated August 19, 1999
			Monsanto Company	OWN	Dated August 19, 1999
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Applicant's/Registrant's Name & Address:

Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
178			Monsanto Company	OWN	Dated August 19, 1999
			Monsanto Company	OWN	Dated August 19, 1999
			Monsanto Company	OWN	Dated August 19, 1999
			Monsanto Company	OWN	Dated February 20, 2001
			Monsanto Company	OWN	Dated March 20, 2001
			Signature		

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Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005		Product: Corn Event MON 863		
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status
			Monsanto Company	OWN
			Monsanto Company	OWN
			Monsanto Company	OWN
			Monsanto Company	OWN
			Monsanto Company	OWN
			Monsanto Company	OWN
Signature		Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.		Date February 13, 2003

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Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[REDACTED]	[REDACTED]	[REDACTED]	Monsanto Company	OWN	Dated January 8, 2002
			Monsanto Company	OWN	Dated April 8, 2002
			Monsanto Company	OWN	Dated September 10, 2002
			Monsanto Company	OWN	Dated September 10, 2002
			Monsanto Company	OWN	Dated August 19, 1999
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 13, 2003	

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Monsanto Company, 600 13th Street, N.W., Suite 660, Washington, D.C. 20005

Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company		Dated August 19, 1999
			Monsanto Company		Dated June 20, 2002
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 13, 2003	

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Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated September 10, 2002
			Monsanto Company		Dated January 13, 2000
			Monsanto Company		Dated February 20, 2001
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	Date February 13, 2003	

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Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005		Product: Corn Event MON 863			
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated February 20, 2001
			Monsanto Company	OWN	Dated March 20, 2002
			Monsanto Company	OWN	Dated May 21, 2001
			Monsanto Company	OWN	Dated November 5, 2001
			Monsanto Company	OWN	Dated November 5, 2001
Signature		Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.		Date February 13, 2003	

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Product: Corn Event MON 863

Ingredient *Bacillus thuringiensis* Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated January 8, 2002
			Monsanto Company	OWN	Dated April 9, 2002
			Monsanto Company	OWN	Dated April 9, 2002
			Monsanto Company	OWN	Dated June 10, 2002
			Monsanto Company	OWN	Dated November 23, 1992
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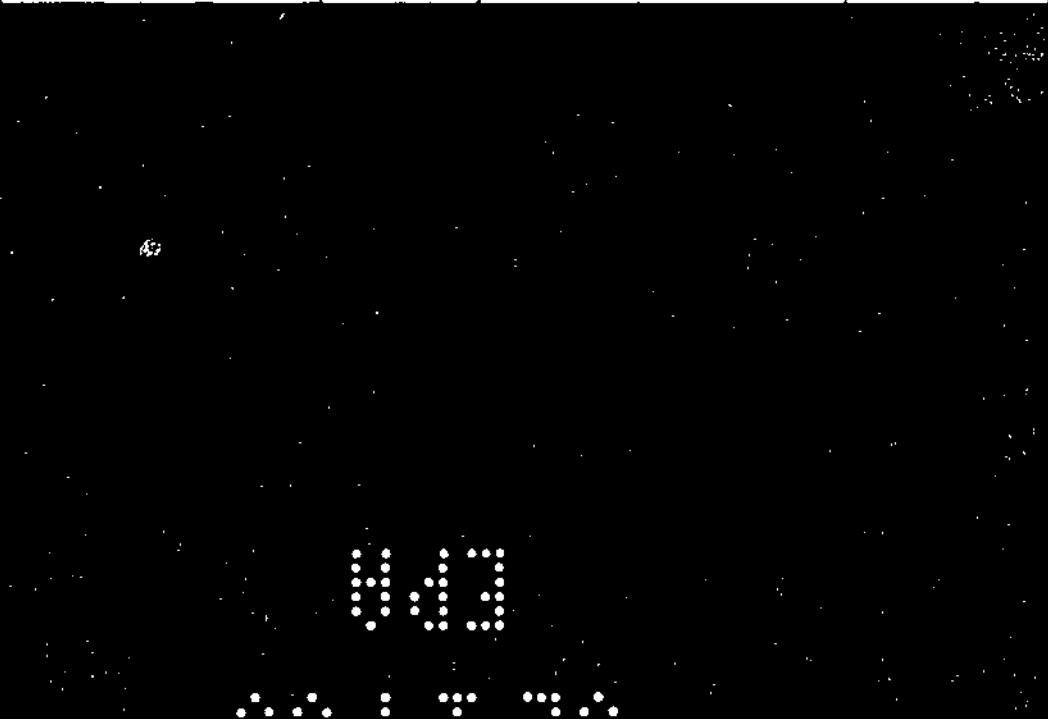
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DATA MATRIX

Date: February 13, 2003			EPA Reg. No./File Symbol: 524-LEI		Page 16 of 16
Applicant's/Registrant's Name & Address: Monsanto Company, 600 13 th Street, N.W., Suite 660, Washington, D.C. 20005			Product: Corn Event MON 863		
Ingredient <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material (vector ZMIR13L) necessary for its production in event MON 863 corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Dated November 23, 1993
			Monsanto Company	OWN	Dated November 23, 1993
				PL	Dated November 23, 1993
Signature			Name and Title Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.		Date February 13, 2003

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy

CONFIDENTIAL STATEMENT OF FORMULA

{CBI Cross Reference Number 1}

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CONFIDENTIAL STATEMENT OF FORMULA

{CBI Cross Reference Number 1}

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PRODUCT LABEL

Five copies of the proposed label for 'Corn Event MON 863: Rootworm Protected Corn' are attached. This label supersedes the label previously submitted to EPA, dated February 11, 2003.

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Corn Event MON 863: Rootworm Protected Corn

[Alternate brand name: *YieldGard Rootworm*[™]: *Rootworm Protection*]

This product is effective in controlling damage caused by corn rootworm larval feeding on corn roots.

Active Ingredient:

Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary for its production (ZMIR13L) in event MON 863 corn.....0.001 - 0.006%

Other Ingredients:

Substance produced by a marker gene and the genetic material necessary for its production (ZMIR13L) in event MON 863 corn.....0.00002 – 0.00003%

Percentage (wt/wt) on a dry weight basis.

Keep Out of Reach of Children

CAUTION

[™] YieldGard Rootworm is a trademark of Monsanto Technology LLC

EPA Registration No. 524-LEI

EPA Establishment No. 524-MO-002

©2003 Monsanto Company
700 Chesterfield Parkway West
St. Louis, MO 63017

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with this labeling.

The following information regarding commercial production must be included in the Event MON 863 Technology Use Guide.

Insect Resistance Management

Growers of Corn Event MON 863: Rootworm Protected Corn must adhere to the following refuge requirements. Growers must plant a structured refuge of at least 20% non-Corn Event MON 863 corn.

Refuge planting options include: blocks, strips or border rows. Refuge acres must be planted within or adjacent to the Corn Event MON 863 field. If blocks are implemented they must be adjacent to the Corn Event MON 863 field. If row strips within a corn field are implemented, then at least 6, and preferably 12 consecutive rows should be planted. If border rows are implemented they should be surrounding the Corn Event MON 863 field.

External refuges must be planted in fields adjacent to the Corn Event MON 863 fields.

The refuge and Corn Event MON 863 acres should be managed under comparable agronomic regimes. Refuge and Corn Event MON 863 acres should both be irrigated if irrigation is used. In regions where corn is cropped continuously, refuge and Corn Event MON 863 acres should be planted in a continuous cropping regime. The refuge may be placed only on first-year corn acres if the Event MON 863 corn is planted on first-year corn acres.

Growers have the option of applying conventional insecticides to the corn refuge for control of corn rootworm larvae. Growers are not permitted to apply agents for control of adult corn rootworm to the refuge as this would render the refuge less effective. If growers opt to treat for other insects present in the refuge while adult corn rootworm are present, then the Corn Event MON 863 acres must be treated in a like manner.

These refuge requirements do not apply to operations engaged in the propagation of inbred seed corn.

Corn Insects Controlled or Suppressed

Corn has been genetically transformed to produce the *B.t.* protein, Cry3Bb1, for control or suppression of the following coleopteran insects:

Western corn rootworm (*Diabrotica virgifera virgifera*)
Northern corn rootworm (*Diabrotica barberi*)
Mexican corn rootworm (*Diabrotica virgifera zaeae*)

CONFIDENTIAL ATTACHMENT

MONSANTO



Amendment of the Application to Register a *Bacillus thuringiensis*
Cry3Bb1 Protein and the Genetic Material Necessary for its
Production (Vector ZMIR13L) in Event MON 863 Corn;
EPA File Symbol 524-LEI

CONFIDENTIAL ATTACHMENT

AUTHOR

Dennis P. Ward, Ph.D.
Regulatory Affairs Manager

DATE

February 13, 2003

SUBMITTING REGISTRANT

Monsanto Company
600 13th Street N.W.
Suite 660
Washington, DC 20005

MONSANTO REFERENCE No.

00-CR-032E-17

187

CONFIDENTIAL BUSINESS INFORMATION

CBI Cross Reference Number 1

This cross reference number noted on a place holder page is used in place of the following whole page at the indicated volume and page references

The deleted Page is attached immediately behind this page.

<u>Pages</u>	<u>Reason for Deletion</u>	<u>FIFRA Reference</u>
37 & 38	Discloses commercial information	§ 10(d)(1)(A), (B) or (C)

Registration # 524-528
Volume 4 of 4

Page ____ is not included in this copy.

Pages 189 through 190 are not included in this copy.

The material not included contains the following type of information:

- ____ Identity of product inert ingredients.
- ____ Identity of product inert impurities.
- ____ Description of the product manufacturing process.
- ____ Description of quality control procedures.
- ____ Identity of the source of product ingredients.
- ____ Sales or other commercial/financial information.
- ____ A draft product label.
- ☒ The product confidential statement of formula.
- ____ Information about a pending registration action.
- ____ FIFRA registration data.
- ____ The document is a duplicate of page(s) ____.
- ____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

MONSANTO



Dennis P. Ward, Ph.D.
Regulatory Affairs Manager
(636) 737-6631

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

February 13, 2003

Document Processing Desk (APPL)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Attn: Phillip O. Hutton, Team Leader 90

Subj: Interim IRM plan for corn event MON 863
Response to your request of February 12, 2003

Dear Mr. Hutton:

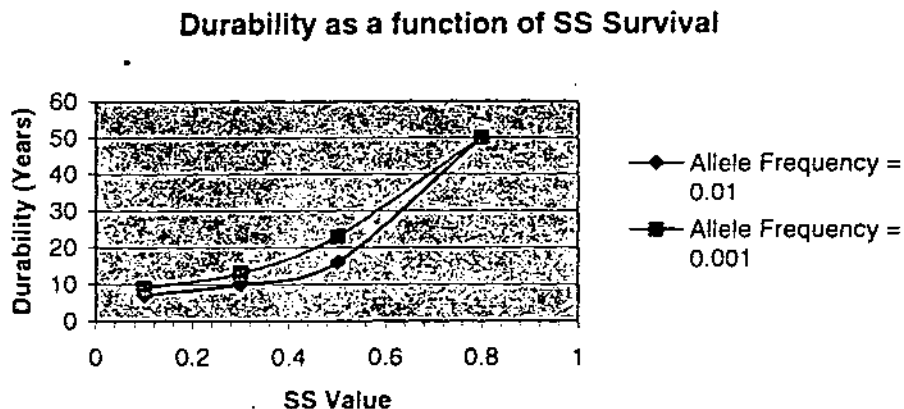
Pursuant to your request for additional product durability simulations with the Caprio model, we are providing the results of simulations with lower survival rates for susceptible rootworms. These durability simulations supplement those provided to the Agency in a letter to Dr. Andersen, dated December 13, 2002.

For this set of durability simulations, we have set the degree of dominance for a resistant allele at 0.8 (a very conservative value) and have run the model with a 20% non-Cry3Bb1 refuge. Durability estimates are computed as a function of resistant rootworm survival and resistance allele frequency. The results over a range of values are presented in Table 1 and graphically presented in Figure 1.

Table 1. Caprio model simulations for corn rootworm rate of resistance to Cry3Bb1 protein produced in corn event MON 863 computed as a function of susceptible insect survival and resistance allele frequency. The degree of dominance for the resistance allele is set at 0.8 and the refuge size is set at 20%.

Survival (%)	Years to Resistance Development	
	Allele Frequency = 0.01	Allele Frequency = 0.001
10	7 years	9 years
30	10 years	13 years
50	16 years	23 years
80	>50 years	>50 years

Figure 1. Graphic representation of Caprio model predictions for product durability as a function of susceptible rootworm survival (SS) and resistance allele frequency. The degree of dominance for the resistance allele is set at 0.8 and the refuge size is set at 20%.



As indicated in our December 13th letter to Dr. Andersen, the results from three years of field efficacy trials with corn event MON 863, from which more than 7,500 plants were rated for root damage, indicate that resistance allele frequency is actually lower than the conservative value of 0.01. Furthermore, the results of these trials indicate that average susceptible insect survival is 50%. Under a scenario where the resistance allele is assumed to be partially dominant (i.e. 0.8), occurring at a frequency of 0.01, and susceptible insect survival is 50%, then an extremely conservative estimate of product durability would be 16 years with a 20% refuge. A more reasonable prediction of product durability, where resistance allele frequency is 0.001, would be 23 years with a 20% refuge.

Should you require any additional information regarding this submission please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (636-737-6631).

Sincerely,

Dennis P. Ward

cc: Mike Mendelsohn, EPA/OPP/BPPD
Russell Schneider, Monsanto
Ty Vaughn, Monsanto

MONSANTO



4

FACSIMILE TRANSMISSION

MONSANTO COMPANY
MAIL ZONE BB3N
700 CHESTERFIELD PARKWAY W.
ST. LOUIS, MO 63017 USA

February 12, 2003

TO : Robyn Rose
EPA / OPP / BPPD

FAX # : 703-308-7026

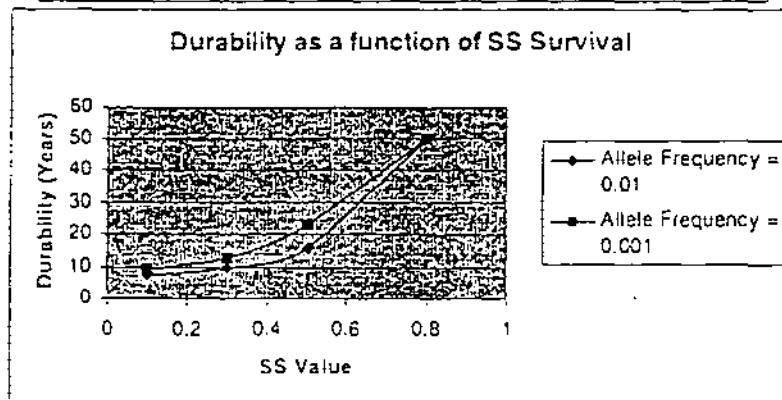
FROM : Dennis P. Ward, Ph.D.
Regulatory Affairs Manager

Telephone: 1-636-737-6631
Telefax: 1-636-737-5943
email: dennis.p.ward@monsanto.com

NUMBER OF PAGES (including cover): 1

MESSAGE: Robyn - The predictions for product durability based on a dominance value of 0.8 with a 20% refuge, modeled as a function of SS survivability and initial allele frequency are shown below. I'll put this in a formal submission to Phil.

SS Value	Allele Frequency = 0.01	Allele Frequency = 0.001
0.1	7 years	9 years
0.3	10 years	13 years
0.5	16 years	23 years
0.8	>50 years	>50 years



1 of 1

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5

Phil, per your request, here is the output from the Caprio model using various SS values. Please let me or Russ know if you need anything else. Sheila Schuette

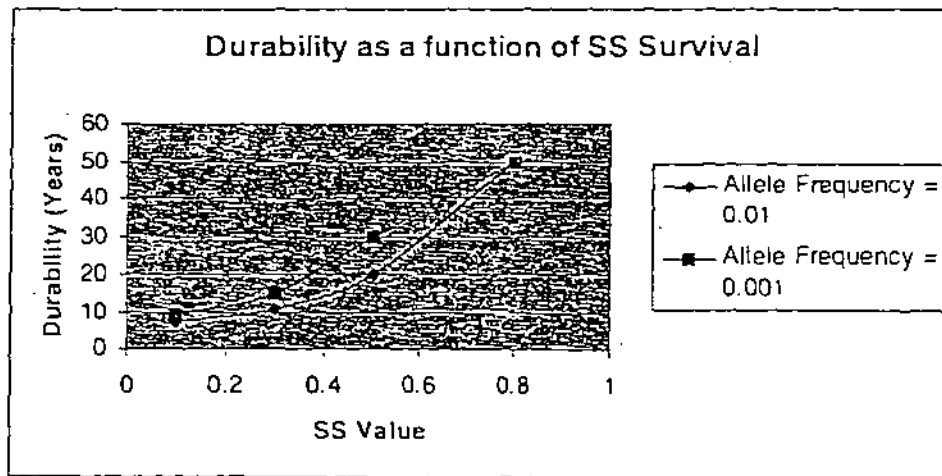
Here is the first run at this and the parameters used. We have good evidence that 0.5 is a realistic value for survival on average. In the most extreme cases, we have seen about 0.17 and as high as 0.95. The dominance value was held at 0.7 and refuge at 20%.

Here are the output values for 20% refuge, heterozygote value of 0.7 (an intermediate level of dominance) and an initial allele frequency of 0.001

SS Value	Durability
0.1	9
0.3	15
0.5	30
0.8	>100

Here are the values when the refuge is 20%, heterozygote frequency is 0.7 and an initial allele frequency is 0.01.

SS Value	Durability
0.1	7
0.3	11
0.5	20
0.8	>100



10/1

194

MONSANTO



①

FACSIMILE TRANSMISSION

MONSANTO COMPANY
MAIL ZONE BB3N
700 CHESTERFIELD PARKWAY W.
ST. LOUIS, MO 63017 USA

February 13, 2003

TO : Mike Mendelsohn
EPA / OPP / BPPD

FAX # : 703-308-7026

FROM : Dennis P. Ward, Ph.D.
Regulatory Affairs Manager

Telephone: 1-636-737-6631

Telefax: 1-636-737-5943

email: dennis.p.ward@monsanto.com

NUMBER OF PAGES (including cover): 3

MESSAGE: Mike – Would you please pass copies of the attached letter on to both Phil and Robyn? Thanks.

1 of 3

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MONSANTO



Dennis P. Ward, Ph.D.
Regulatory Affairs Manager
(636) 737-6631

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

February 13, 2003

Document Processing Desk (APPL)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Attn: Phillip O. Hutton, Team Leader 90

Subj: Interim IRM plan for corn event MON 863
Response to your request of February 12, 2003

Dear Mr. Hutton:

Pursuant to your request for additional product durability simulations with the Caprio model, we are providing the results of simulations with lower survival rates for susceptible rootworms. These durability simulations supplement those provided to the Agency in a letter to Dr. Andersen, dated December 13, 2002.

For this set of durability simulations, we have set the degree of dominance for a resistant allele at 0.8 (a very conservative value) and have run the model with a 20% non-Cry3Bb1 refuge. Durability estimates are computed as a function of resistant rootworm survival and resistance allele frequency. The results over a range of values are presented in Table 1 and graphically presented in Figure 1.

Table 1. Caprio model simulations for corn rootworm rate of resistance to Cry3Bb1 protein produced in corn event MON 863 computed as a function of susceptible insect survival and resistance allele frequency. The degree of dominance for the resistance allele is set at 0.8 and the refuge size is set at 20%.

Survival (%)	Years to Resistance Development	
	Allele Frequency = 0.01	Allele Frequency = 0.001
10	7 years	9 years
30	10 years	13 years
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80	>50 years	>50 years

00-CR-032E-18

2043

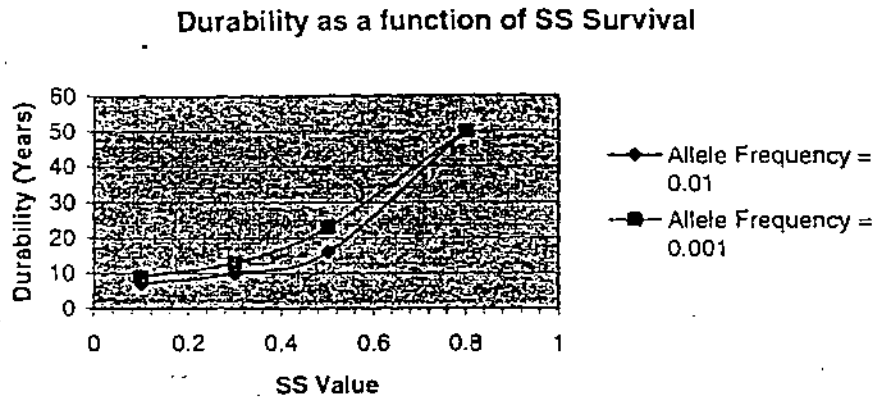
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Mr. P. Hutton

02/13/2003

Page -2-

Figure 1. Graphic representation of Caprio model predictions for product durability as a function of susceptible rootworm survival (SS) and resistance allele frequency. The degree of dominance for the resistance allele is set at 0.8 and the refuge size is set at 20%.



As indicated in our December 13th letter to Dr. Andersen, the results from three years of field efficacy trials with corn event MON 863, from which more than 7,500 plants were rated for root damage, indicate that resistance allele frequency is actually lower than the conservative value of 0.01. Furthermore, the results of these trials indicate that average susceptible insect survival is 50%. Under a scenario where the resistance allele is assumed to be partially dominant (i.e. 0.8), occurring at a frequency of 0.01, and susceptible insect survival is 50%, then an extremely conservative estimate of product durability would be 16 years with a 20% refuge. A more reasonable prediction of product durability, where resistance allele frequency is 0.001, would be 23 years with a 20% refuge.

Should you require any additional information regarding this submission please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (636-737-6631).

Sincerely,

Dennis P. Ward

cc: Mike Mendelsohn, EPA/OPP/BPPD
 Russell Schneider, Monsanto
 Ty Vaughn, Monsanto

00-CR-032E-18

3 of 3

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2



Robyn Rose

02/19/03 03:43 PM

To: Robyn Rose
cc:
cc:
Subject: Rootworm Bt corn

----- Forwarded by Phil Hutton/DC/USEPA/US on 02/07/03 12:51 PM -----



Fred Gould
<fred_gould@ncsu.edu
u>

02/06/03 04:25 PM

To: Sharlene Matten/DC/USEPA/US@EPA,
rose.robin@epamail.epa.gov, Phil Hutton/DC/USEPA/US@EPA
cc:
Subject: Rootworm Bt corn

Phil,

I contacted Sharlene about the Monsanto written response to the EPA SAP and she said that I should contact you.

Monsanto indicates that the SAP concerns about initial resistance gene frequencies, and about quantitative genetic resistance are unwarranted based on theory and based on experiments that have been performed.

The science in the Monsanto response is lacking. First of all they do not take into account the fact that alleles for quantitative genetic resistance are expected, based on theory and past experiments to be at higher frequencies than major resistance genes. The only times when resistance due to major genes and to quantitative genetic variation is expected to develop at the same rate is when gene frequencies are comparable. When there is a high degree of quantitative genetic variation resistance can evolve MUCH faster.

Monsanto indicates that the experiments they describe prove that resistance allele frequencies are low. This is not true. Those experiments would only have picked up major non-recessive genes for resistance. They could not detect anything about minor genes.

Monsanto only looks at selection pressure that could be inferred from larval mortality. As written in the 2002 EPA SAP document, that is likely to be an underestimate of the selection pressure, so it would underestimate the rate of resistance development.

Monsanto never addresses the issue of once you start with a 20% refuge it will be impossible to go back to a substantially larger refuge, for social reasons.

I feel like Monsanto keeps avoiding the fact that the previous EPA SAPs (1998, 2001) specifically stated that the BT cultivars had to be High Dose.

Monsanto has not provided scientific justification for a moderate dose approach.

If you need more details, please let me know.

Fred

1 of 1

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MONSANTO



Dennis P. Ward, Ph.D.
Regulatory Affairs Manager
(636) 737-6631

MONSANTO COMPANY
600 13TH STREET, N.W.
SUITE 660
WASHINGTON, D.C. 20005
PHONE (202) 783-2460
FAX (202) 783-2468
<http://www.monsanto.com>

February 11, 2003

Document Processing Desk (APPL)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Attn: Phillip O. Hutton, Team Leader 90

Subj: Amendment to application for registration of Corn Event MON 863
EPA File Symbol 524-LEI

Dear Mr. Hutton:

In response to a request received from Mr. Mike Mendelsohn, we are providing a revised label and Confidential Statement of Formula for Corn Event MON 863.

Enclosed with this submission are the following materials:

- Application for Pesticide (EPA Form 8570-1)
- Product label (5 copies)
- Confidential attachment

Except for the materials contained in the Confidential Attachment and subject to the provisions of FIFRA Section 10(g), Monsanto does not object to placement of materials contained in this submission in the Public Docket.

Should you require any additional information regarding this submission please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (636-737-6631).

Sincerely,

Dennis P. Ward, Ph.D.
Regulatory Affairs Manager

Mr. P. Hutton
2/11/2003
Page 2 of 15

Att: Administrative materials

cc: Mike Mendelsohn, EPA/OPP/BPPD
Russell Schneider, Monsanto



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier
Number

Application for Pesticide – Section I

1. Company/Product Number File Symbol 524-LEI	2. EPA Product Manager Phillip O. Hutton	3. Proposed Classification
Company/Product (Name) Corn Event MON 863	PM # 90	<input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
5. Name and Address of Applicant (Include ZIP Code) Monsanto Company 600 13 th St., N.W., Suite 660 Washington, DC 20005 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section – II

<input checked="" type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated
<input type="checkbox"/> Resubmission in response to Agency letter dated	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification – Explain below.	<input type="checkbox"/> Other – Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Submission of revised labeling and CSF

Section – III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per Container	If "Yes" Package wgt. No. per Container
Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

Section – IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name Russell P. Schneider	Title Regulatory Affairs Director	Telephone No. (Include Area Code) (202) 303-2866
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Affairs Manager	201
4. Typed Name Dennis P. Ward Tel. (636) 737-6631	5. Date February 11, 2003	

CONFIDENTIAL STATEMENT OF FORMULA

{CBI Cross Reference Number 1}

PRODUCT LABEL

The subject of this submission is a request for registration of *Bacillus thuringiensis* Cry3Bb1 protein and the genetic material (ZMIR13L) necessary for its production in all corn lines and varieties containing event MON 863. A full and unrestricted FIFRA section 3 registration is being sought to support commercialization of this product. Five copies of the proposed label for 'Corn Event MON 863: Rootworm Protected Corn Seed' are attached. This label supersedes the label previously submitted to EPA on February 4, 2003.

The proposed label is for the pesticidal protein, Cry3Bb1, contained within event MON 863 corn seed.

Plant-Incorporated Protectant Label

Corn Event MON 863: Rootworm Protected Corn Seed

[Alternate brand name: *YieldGard® Rootworm: Rootworm Protection*]

This package contains corn rootworm-protected corn seed producing Cry3Bb1, an insecticidal protein from *Bacillus thuringiensis (B.t.)*. This protein is effective in controlling damage caused by corn rootworm (*Diabrotica* spp.) larval feeding on corn roots.

Active Ingredient:

Corn-produced *B.t.* Cry3Bb1 protein and the genetic material (vector ZMIR13L) necessary for its production in corn event MON 863.....0.0096%

Other Ingredients:

Substance produced by a marker gene and the genetic material (vector ZMIR13L) necessary for its production in corn event MON 863.....<0.00001%

Percentage (wt/wt) on a dry weight basis.

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

® YieldGard is a trademark of Monsanto Technology LLC.

EPA Registration No. 524-528

EPA Establishment No. 524-MO-002

©2003 Monsanto Company
700 Chesterfield Parkway West
St. Louis, MO 63017

NET CONTENTS _____

Corn Event MON 863: Rootworm Protected Corn Seed

DIRECTIONS FOR USE

It is a violation of Federal law to use this seed in any manner inconsistent with this labeling.

Corn Insects Controlled or Suppressed

Corn has been genetically transformed to produce the *B.t.* protein, Cry3Bb1, for control or suppression of the following coleopteran insects:

Western corn rootworm (*Diabrotica virgifera virgifera*)

Northern corn rootworm (*Diabrotica barberi*)

Mexican corn rootworm (*Diabrotica virgifera zeae*)

Insect Resistance Management

Growers of Corn Event MON 863: Rootworm Protected Corn must adhere to the following refuge requirements. Growers must plant a structured refuge of at least 20% non-Corn Event MON 863 corn.

Refuge planting options include: blocks, strips or border rows. Refuge acres must be planted within or adjacent to the Corn Event MON 863 field. If blocks are implemented they must be adjacent to the Corn Event MON 863 field. If row strips within a corn field are implemented, then at least 4, and preferably 12 consecutive rows should be planted. If border rows are implemented they should be surrounding the Corn Event MON 863 field.

External refuges must be planted in fields adjacent to the Corn Event MON 863 fields.

The refuge and Corn Event MON 863 acres should be managed under comparable agronomic regimes. Refuge and Corn Event MON 863 acres should both be irrigated if irrigation is used. In regions where corn is cropped continuously, refuge and Corn Event MON 863 acres should be planted in a continuous cropping regime. The refuge may be placed only on first-year corn acres if the Event MON 863 corn is planted on first-year corn acres.

Growers have the option of applying conventional insecticide treatments, including seed treatments or granular insecticides, to the corn refuge for control of corn rootworm larvae. Growers are not permitted to apply agents for control of adult corn rootworm to the refuge as this would render the refuge less effective. If growers opt to treat for other insects present in the refuge while adult corn rootworm are present, then the Corn Event MON 863 acres must be treated in a like manner.

These refuge requirements do not apply to operations engaged in the propagation of inbred seed corn.

MONSANTO



Amendment of the Application to Register a *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in Corn Event MON 863; EPA File Symbol 524-LEI

CONFIDENTIAL ATTACHMENT

AUTHOR

Dennis P. Ward, Ph.D.
Regulatory Affairs Manager

SUBMISSION DATE

February 11, 2003

SUBMITTING REGISTRANT

Monsanto Company
600 13th Street N.W.
Suite 660
Washington, DC 20005

MONSANTO REFERENCE No.

00-CR-032E-16

206

CONFIDENTIAL BUSINESS INFORMATION

CBI Cross Reference Number 1

This cross reference number noted on a place holder page is used in place of the following whole page at the indicated volume and page references

The deleted Page is attached immediately behind this page.

<u>Page</u>	<u>Reason for Deletion</u>	<u>FIFRA Reference</u>
4	Discloses commercial information	§10(d)(1)(A), (B) or (C)

Registration 524-528
Volume 4 of 4

Page 208 is not included in this copy.

Pages ____ through ____ are not included in this copy.

The material not included contains the following type of information:

- ____ Identity of product inert ingredients.
- ____ Identity of product inert impurities.
- ____ Description of the product manufacturing process.
- ____ Description of quality control procedures.
- ____ Identity of the source of product ingredients.
- ____ Sales or other commercial/financial information.
- ____ A draft product label.
- ☒ The product confidential statement of formula.
- ____ Information about a pending registration action.
- ____ FIFRA registration data.
- ____ The document is a duplicate of page(s) ____.
- ____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

MONSANTO



Dennis P. Ward, Ph.D.
Regulatory Affairs Manager
(636) 737-6631

MONSANTO COMPANY
600 13TH STREET, N.W.
SUITE 660
WASHINGTON, D.C. 20005
PHONE (202) 783-2460
FAX (202) 783-2468
<http://www.monsanto.com>

February 4, 2003

Document Processing Desk (APPL)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Attn: Phillip O. Hutton, Team Leader 90

Subj: Amendment to application for registration of Corn Event MON 863
EPA File Symbol 524-LEI

Dear Mr. Hutton:

In response to a request received from Mr. Mike Mendelsohn, we are providing an updated Data Matrix for Monsanto's application to register Corn Event MON 863. This updated matrix indicates which of the data requirements for microbial pesticides (40 CFR §158.740) have been satisfied or are not applicable to Cry3Bb1.

Monsanto is also providing revised labeling for Corn Event MON 863 as part of this amendment. Lastly, we are notifying the Agency of the alternate brand name, *YieldGard Rootworm: Rootworm Protection*.

Enclosed with this submission are the following materials:

- Application for Pesticide (EPA Form 8570-1)
- Certification with Respect to Citation of Data (EPA Form 8570-34)
- Data Matrix (EPA Form 8570-35)
- Product label (5 copies)

Subject to the provisions of FIFRA Section 10(g), Monsanto does not object to placement of materials contained in this submission in the Public Docket.

Should you require any additional information regarding this submission please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (636-737-6631).

Sincerely,

A handwritten signature in black ink, appearing to read 'D. Ward', with a large, loopy flourish at the end.

Dennis P. Ward, Ph.D.
Regulatory Affairs Manager

Att: Administrative materials

cc: Mike Mendelsohn, EPA/OPP/BPPD
Russell Schneider, Monsanto

MONSANTO



Dennis P. Ward, Ph.D.
Regulatory Affairs Manager
(636) 737-6631

Monsanto Company
700 Chesterfield Pkwy West
Chesterfield, MO 63017
PHONE (314) 694-1000
FAX (636) 737-5943
<http://www.monsanto.com>

February 4, 2003

Document Processing Desk (APPL)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Attn: Phillip O. Hutton, Team Leader 90

Subj: Amendment to application for registration of Corn Event MON 863
EPA File Symbol 524-LEI

Dear Mr. Hutton:

In response to a request received from Mr. Mike Mendelsohn, we are providing an updated Data Matrix for Monsanto's application to register Corn Event MON 863. This updated matrix indicates which of the data requirements for microbial pesticides (40 CFR §158.740) have been satisfied or are not applicable to Cry3Bb1. Monsanto is requesting a waiver from the requirement to provide the studies that are deemed not applicable; justification for these data waivers are contained within the attached data matrix.

Monsanto is also providing revised labeling for Corn Event MON 863 as part of this amendment. Lastly, we are notifying the Agency of the alternate brand name, *YieldGard Rootworm: Rootworm Protection*.

Enclosed with this submission are the following materials:

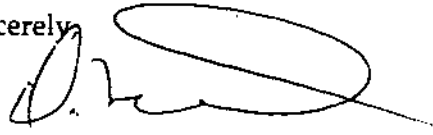
- Application for Pesticide (EPA Form 8570-1)
- Certification with Respect to Citation of Data (EPA Form 8570-34)
- Data Matrix (EPA Form 8570-35)
- Product label (5 copies)

Subject to the provisions of FIFRA Section 10(g), Monsanto does not object to placement of materials contained in this submission in the Public Docket.

Mr. P. Hunton
2/4/2003
Page 2 of 45

Should you require any additional information regarding this submission please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (636-737-6631).

Sincerely,

A handwritten signature in black ink, appearing to be "D. Ward", written over a horizontal line.

Dennis P. Ward, Ph.D.
Regulatory Affairs Manager

Att: Administrative materials

cc: Mike Mendelsohn, EPA/OPP/BPPD
Russell Schneider, Monsanto

FOR OFFICIAL USE ONLY

FILE SYMBOL

LEI

REGISTRATION NO.

524

CONFIDENTIAL STATEMENT OF FORMULA ENCLOSED

DATE SUBMITTED	SUBMITTED BY: (✓)	
	APPLICANT	BASIC SUPPLIER
6/20/60		

Do Not Write Comments,
Formula, or Parts of Formula
on This Envelope

NOTE

It shall be unlawful—for any person to use for his own advantage or to reveal, other than to the Secretary, or officials or employees of the United States Department of Agriculture or other Federal agencies, or to the courts in response to a subpoena, or to physicians, and in emergencies to pharmacists and other qualified persons, for use in the preparation of antidotes, in accordance with such directions as the Secretary may prescribe, any information relative to formulas of products acquired by authority of Section 4 of the "Federal Insecticide, Fungicide, and Rodenticide Act."

Registration 524-528
Volume 4 of 4

Page ____ is not included in this copy.

Pages 214 through 219 are not included in this copy.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
- ☐ Identity of product inert impurities.
- ☐ Description of the product manufacturing process.
- ☐ Description of quality control procedures.
- ☐ Identity of the source of product ingredients.
- ☐ Sales or other commercial/financial information.
- ☒ A draft product label.
- ☒ The product confidential statement of formula.
- ☐ Information about a pending registration action.
- ☐ FIFRA registration data.
- ☐ The document is a duplicate of page(s) _____.
- ☐ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
